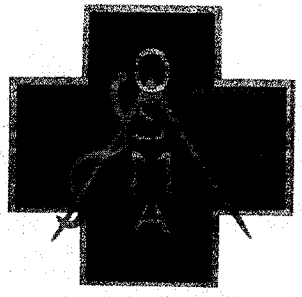

Docket No. 00D-0053
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fischers Lane Room 1061, (HFA-305)
Rockville, MD 20852

Re: Reuse of Single Use Devices

Dear Sir/Madam:

The Orthopedic Surgical Manufacturers Association (OSMA) is a nonprofit organization whose membership consists solely of manufacturers of orthopedic surgical appliances, implants, instruments or equipment. Among these devices several member companies manufacture single use surgical devices for use in general and orthopedic procedures. As a group of manufacturers of many single use devices, we feel that it is important to help the FDA in making a decision regarding the regulation of third-party reprocessors. The primary intent of this document is to provide our perspective on several of the more important aspects of the Agency's proposed strategy and to describe the effect of reprocessing on many of our single use devices.

Regulatory Classification and Submissions:
OSMA agrees with the Agency's commitment to regulate reprocessors and OEMs using the same criteria. To this end, there is currently a classification system that is both adequate and applicable for the vast majority of devices. However, the current system does not adequately address the risks associated with reprocessing class I or II exempt devices. Under the current system, a class I or II exempt device that has a moderate or high risk associated with the reprocessing and re-use of the device would remain exempt from premarket submissions. This does not adequately address the concerns regarding safety and effectiveness that are introduced during reprocessing. In these cases, the exempt classification is not acceptable and a premarket submission should be required because the patient could be subjected to unreasonable and substantial risk of illness or injury.

ORTHOPEDIC SURGICAL MANUFACTURERS ASSOCIATION
An Association of Manufacturers Devoted to the Interest of the Surgical Patient
1962 Deep Valley Cove
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e-mail: rgames@bellsouth.net

Reprocessors should be required to make model specific premarket submissions (510(k)s or PMAs) for any product they intend to reprocess. Reprocessing alters the intended use of a single use device, and consequently creates a new device. Furthermore since reprocessing raises new concerns of safety and efficacy, this requirement must include products which may have been exempt from submission as a single use device. These premarket submissions should include all information specified in the April 1996 guidance document on reusable devices, Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance and in Labeling- Regulatory Requirements for Medical Devices (FDA 89-423, issued 9/01/1989). Specifically submissions should include the information, testing and validations required to support a claim that a device may be reused (i.e., cleaning, sterilization, and performance, etc.) and how many times, in addition to how the reuse will be tracked.

Definitions:
Reprocessing – The proposed definition of reprocessing is not suitable. Initial sterilization of a non-sterile device should be excluded from the text since this activity is the initial process with a new product, and should not be confused with the secondary processing of a used product.

Consensus Standards:
The agency has suggested the development and use of consensus standards to assess the safety and effectiveness of reprocessed single use devices. We are concerned about the practicality of this approach. FDA staff has stated that reprocessing needs to be considered on a model by model basis – this would suggest standards must similarly be considered. Furthermore, based on our experiences we oppose any proposal to permit reprocessors the option to issue Declaration of Conformance to standards until there is sufficient history and evidence of reprocessor performance to ensure device safety and effectiveness.

Labeling Requirements:
The decision to label a device as single use is based on research during product development. This entails testing of the physical characteristics to determine whether the reuse of a device would place a patient at unreasonable and substantial risk of illness or injury. Concerns of infection and contamination need to be addressed as well as the integrity of the product. A manufacturer must consider whether the device could be safely and effectively used multiple times on the same patient or different patients.

By changing a single use device to a reusable device the reprocessor becomes the *de facto* manufacturer of the device and must take responsibility for all aspects of the device design and manufacture. This includes all required labeling and instructions for use as defined in 21 CFR Part 801, plus an indication of the number of uses/reuses that have occurred. Many of the reused devices that we reviewed do not include any Instructions for Use (IFU). The package states "See Original Manufacturers Operating Instructions" (Attachment 1 Photographs of reprocessed product labels). The reprocessor is making an assumption that the hospital still has copies of the OEMs instructions and that the

instructions are relevant for reprocessed blades. Reprocessors should not be permitted to abdicate their responsibilities for labeling in this manner.

Moreover, the labels often do not include lot numbers or expiration dates, thus imparing the ability to track a device and appropriately comply with Medical Device Reporting requirements. When a device is reprocessed, the OEM (original equipment manufacturer) trademark is still on the device and therefore is held accountable for adverse events or device failures. The third party reprocessor's name is solely on the packaging material, which is typically disposed of when preparing for the procedure. If an adverse event occurs during the procedure, the only label on the device is that of the OEM. This creates a loophole in the accountability of MDRs. When an OEM receives a MDR it is virtually impossible for the OEM to know whether the device was reprocessed. Clinicians may not be aware that the device was reprocessed and therefore will report to the manufacturer whose name is on the device. In addition to the lack of traceability to the third party reprocessor, hospitals do not want to inform the OEM in fear of bad publicity that they are reusing single use devices. The third party reprocessor does not receive any information about the adverse event or device failure and the OEM processes the MDR/complaint even though the device has been reprocessed. Thus, it is not surprising that third party reprocessors have few MDRs. Clearly, third-party reprocessors do not have a true representation of MDRs and the OEM is held accountable for the MDRs that should be reported to the third-party reprocessor.

To avoid mislabeling and patient illness or injury, the reprocessor should be required to remove the original manufacturer's name, identity and/or trademarks from the product – if not the device should be considered mislabeled. It is not enough for the reprocessor to label the package, since during use the package is quickly removed and discarded, and the device appears as an OEM original product, thereby misleading the user and misrepresenting the product. These devices should also have a symbol or marking of some sort that allows the end user to immediately identify that they have been reprocessed.

Product Specific Issues

In accordance with current regulations, all claims made of a product's performance, should be supported with sound scientific evidence. OSMA believes that the claim many reprocessors make which states that reprocessed cutting accessories are "Good or Better than New" is falsely represented. The cutting accessories produced by various member companies in OSMA are precision instruments, some designed to rotate up to 100,000 RPM, while delivering precise, clean cuts. Attempts to sharpen a used device only removes additional material and further destabilizes and depletes the device. Metal flakes and broken tips or fragments are pre-existing concerns and these are multiplied when units have been reworked. Dull, flaking or mis-dimensioned cutting accessories may lead to increased surgical time and/or poor surgical outcomes, accelerated handpiece wear due to the increased power needed to run the handpiece and injuries to the patient and healthcare worker. In

addition, loss of cutting effectiveness leads to increased heat at the bone – device interface and may cause thermal necrosis of the bone.

Clearly these single use products cannot be effectively reprocessed and compromise patient safety and device performance. We have inspected and tested many products reprocessed by third party organizations, and in all cases found the products unfit for use. To illustrate this, representative companies, including Smith & Nephew and Stryker Instruments, have compiled data for several designs and styles of arthroscopic blades (classified by the Agency as Class I exempt, under 21 CFR 878.1100, Arthroscopic Accessories, Code NBH), burrs, surgical drills, and saw blades, (Class I exempt under 21 CFR 878.4820 product codes GFF, GEY, GET, GFA, and DWH). This data shows the reprocessed devices perform inadequately and place the patient at a higher risk of injury by compromising safety and effectiveness for profit. Because we believe the current Classification system is both adequate and appropriate, we used the risk categorization scheme, found in the FDA draft guidance document, to demonstrate the risk associated with reprocessing these devices is higher than assessed by the current draft guidance documents.

I. Risk of Infection

Is the SUD a critical device?

Yes, blades, drills, and burrs are considered critical devices because they come into contact with a normally sterile area.

Does postmarket information suggest that using the reprocessed SUD may present an icreased risk of infection when compared to the use of an SUD that has not been reprocessed.

We do not have specific complaints of infection as the result of reuse of these products.

However, cutting accessories that had been reprocessed show that the refurbished/reprocessed devices all had the potential to have sterility concerns for the following reasons: penetration of the packaging materials by the blade, poor seal quality, and the use of sterilization methods which may not been fully validated for use in small lumen devices. (See Attachment 2 for photographs of packaging used for refurbished devices and packaging for new devices) Photographs II-3 and II-4 demonstrate significant particulate matter within the sterile packaging.

Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?

Yes our data demonstrates that it is virtually impossible to adequately clean a used cutting accessory.

When reprocessed blades were inspected, blades frequently contained contaminants (consistent with adherent tissue and blood) from previous surgical procedures. The design of the blades makes it difficult if not impossible to remove all of the debris from the previous surgery. (See Attachment 4 for photographs of refurbished devices with blood and tissue on the device). Specifically all inner blades have an inaccessible narrow lumen (<5mm) which is the aspiration path for tissue, etc. during surgery. Additionally, curved blades can not be disassembled, and they include a spring section that cannot be cleaned.

End of Flow Chart 1 – High Risk Device

Flow Chart 2 – Inadequate Performance

Does a reusable device exist that has an equivalent design and the same intended use as the SUD?

No, the reusable cutting accessories currently on the market are specifically designed from different materials to withstand the rigors of multiple uses.

Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the SUD has been adequately cleaned and sterilized/disinfected.

No

Does Postmarket information suggest that using reprocessed SUD may present an increased risk of injury when compared to an SUD that has not been reprocessed.

While there are no specific complaints that could be directly tied to the reprocessing cutting accessories, we have examined many blades and burrs that had been reprocessed and found the following:

1. Dulled cutting surfaces, flattened cutting teeth and edge form damage

   A sharp cutting edge is necessary for optimum performance. The design of these devices make it difficult if not impossible to sharpen the blade without damaging other aspects of the device. Use of a dull blade will rip the tissue as opposed to cutting the tissue. The ripped tissue is more likely to clog the inner lumen of the blade than cut tissue.

   Edge form damage in the form of burrs, metal filings, thinning of base metal of the cutting teeth, modification of angles of the cutting surfaces etc. would likely lead to reduced cutting efficacy, shedding of metal fragments and fracture of metal fragments into the surgical site. (See attachment 3 for photographs of new, unused disposable blades and refurbished blades that would have significant performance issues)

2. Binding/seizing at startup

   Damage to hub components from overuse and/or friction from bent blade shafts have been found. These devices have a coating on the inner blade to ensure that it rotates smoothly inside the outer blade. When this coating is damaged it results in poor rotation and binding and seizing of blades upon startup of the blade.

3. Cracking in the plastic hubs

   Cracking in the plastic hubs, ranging from microscopic to gross cracking (visible to the naked eye) has been observed in both refurbished and reprocessed blades. In some blades, portions of the plastic components have been missing entirely. This damage would result in hub fractures and loss of blade control during surgery.

Could failure of the device cause death, serious injury or permanent impairment?

No

Are there recognized consensus performance standards, performance tests recommended by the OEM or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?

No.

Can visual inspection determine if performance has been affected?

No.

Does the SUD contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?

Some of these devices have a coating on the inner blade to ensure that it rotates smoothly inside the outer blade. When this coating is damaged it results in poor rotation and binding/seizing of blades upon startup of the blade.

Are there recognized consensus standards, , performance tests recommended by the OEM or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?

No.

End Flow Chart 2 – High Risk

Stryker Instruments has conducted a study representing a total of 213 reprocessed devices that had been removed from various health care facilities across the country. These devices were inspected by a team of highly skilled engineers against Device Master Record results of the study showed 42.2% mislabeled devices, 38.0% devices with Compromised Condition and 10.8% Packaging Flaws. The full study report can be found in attachment 6.

In addition to the study provided by Stryker Instruments, Smith & Nephew has provided Photographs representing the compromised condition, labeling and impaired safety and effectiveness of arthroscopic blades which can be found in attachments 1-5.

Conclusion:

OSMA has clearly demonstrated why the agency should hold reprocessors of single use devices to the same standard as they hold the original manufacturer. Based on the compilation of the study conducted by Stryker Instruments and the review of reprocessed arthoscopic blades by Smith & Nephew, we have shown that these reprocessed cutting accesories pose a significantly higher risk of infection than the original products. Edges of the blades become dull from reuse the blades will be significantly less effective as a cutting tool than when they were new. This risk promulgates the importance of establishing ways to address the mislabeling issues (removing the OEMs trademark), product classification and submission requirements.

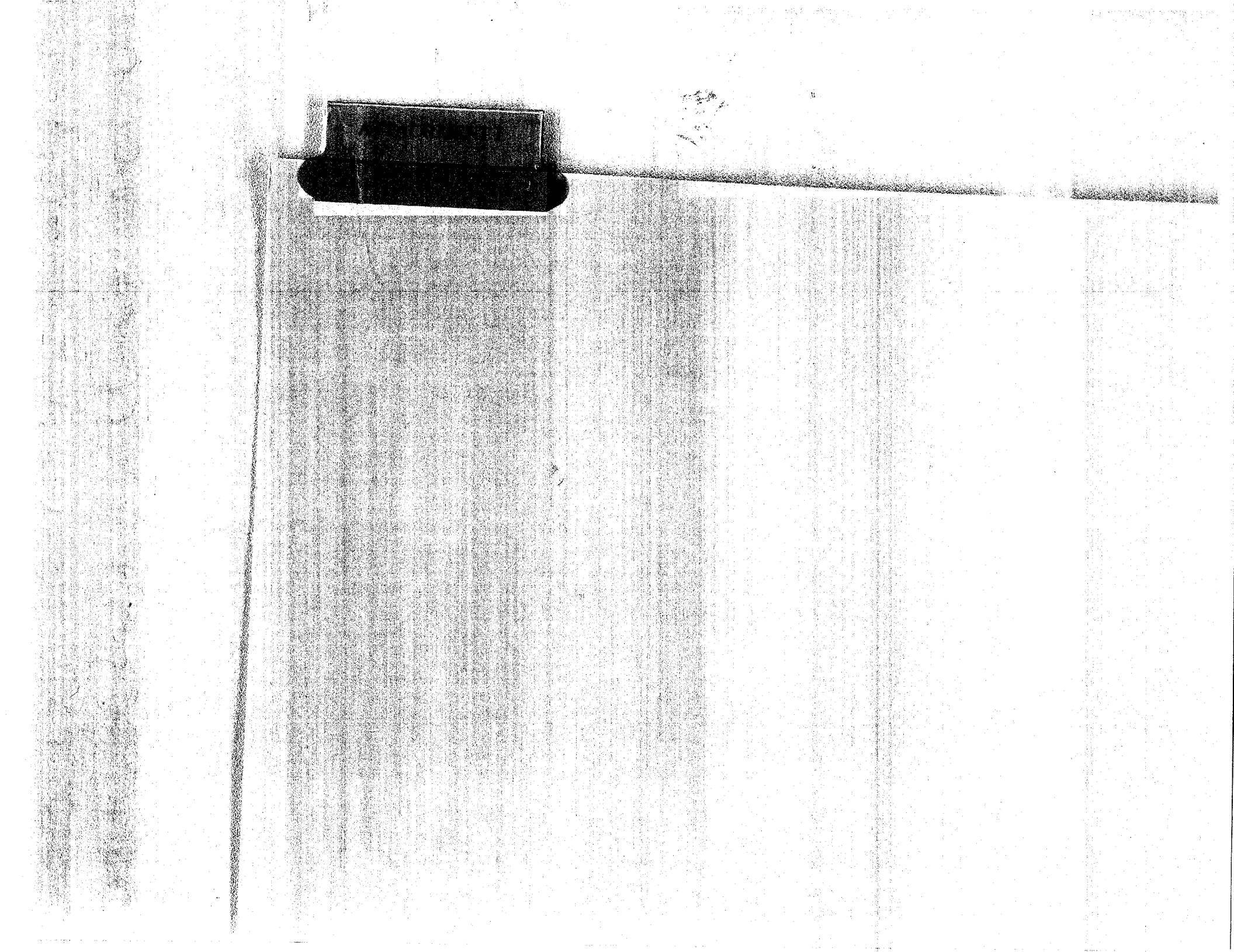
I hope the photographs and study results that we have provided are useful to you in reviewing the very dangerous process of reusing devices designed to be single use. Please do not hesitate to contact me at 616-323-7700 x3386 if you have further questions.

Sincerely,

Suzanne M. Velazquez
OSMA Chair-Reprocessing and Re-use of Single Use Devices

Attachments

Attachment 1	Photographs of Smith and Nephew Inc,., original labels and refurbished product labels
Attachment 2	Photographs of Smith and Nephew Inc. packaged blades and refurbished packaged blades
Attachment 3	Photographs of new blades and refurbished blades
Attachment 4	Photographs of blades which were not adequately cleaned
Attachment 5	Mislabeled refurbished blades
Attachment 6	Stryker Instruments Study on re-used single use devices

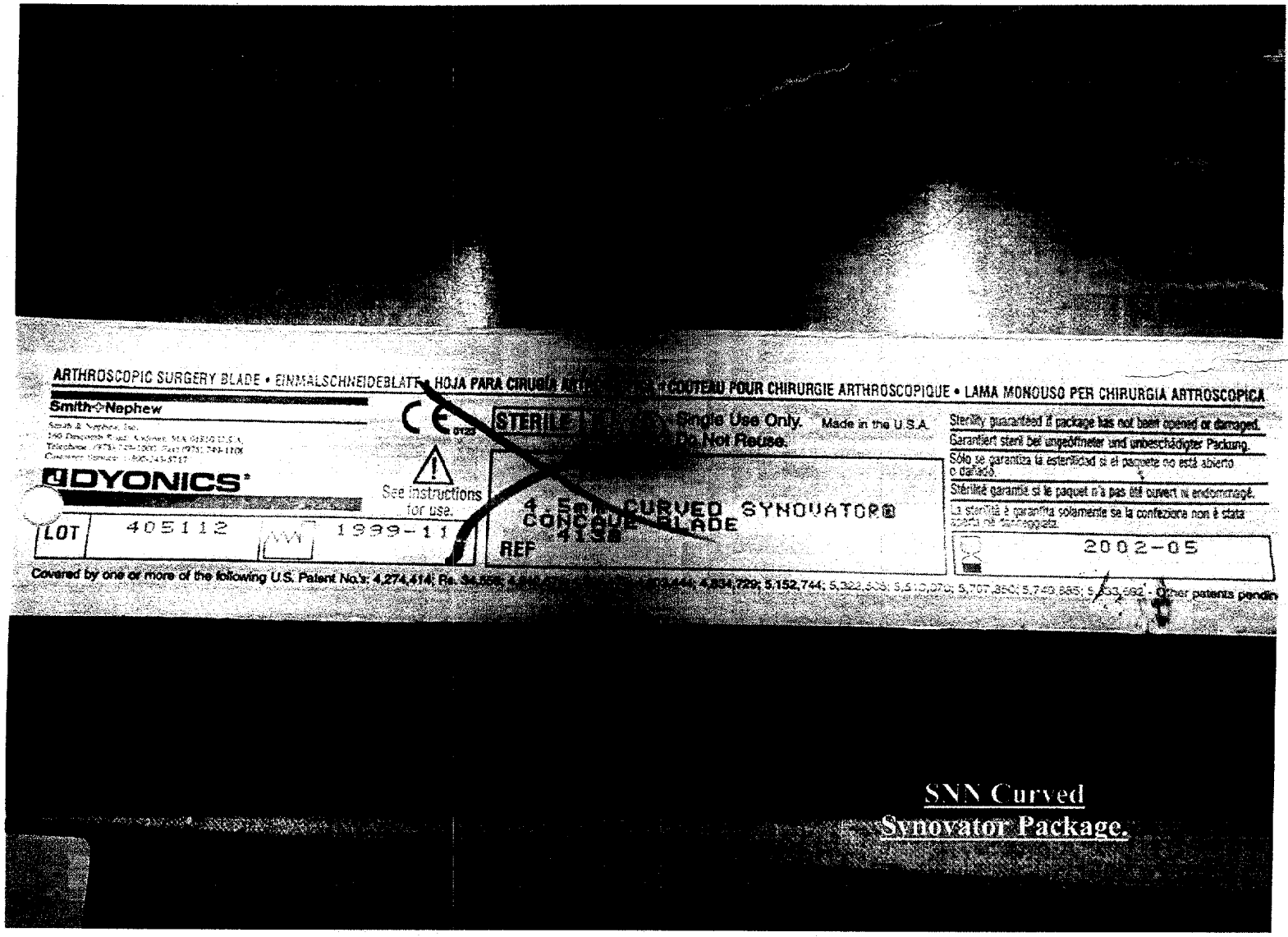


ATTACHMENT I

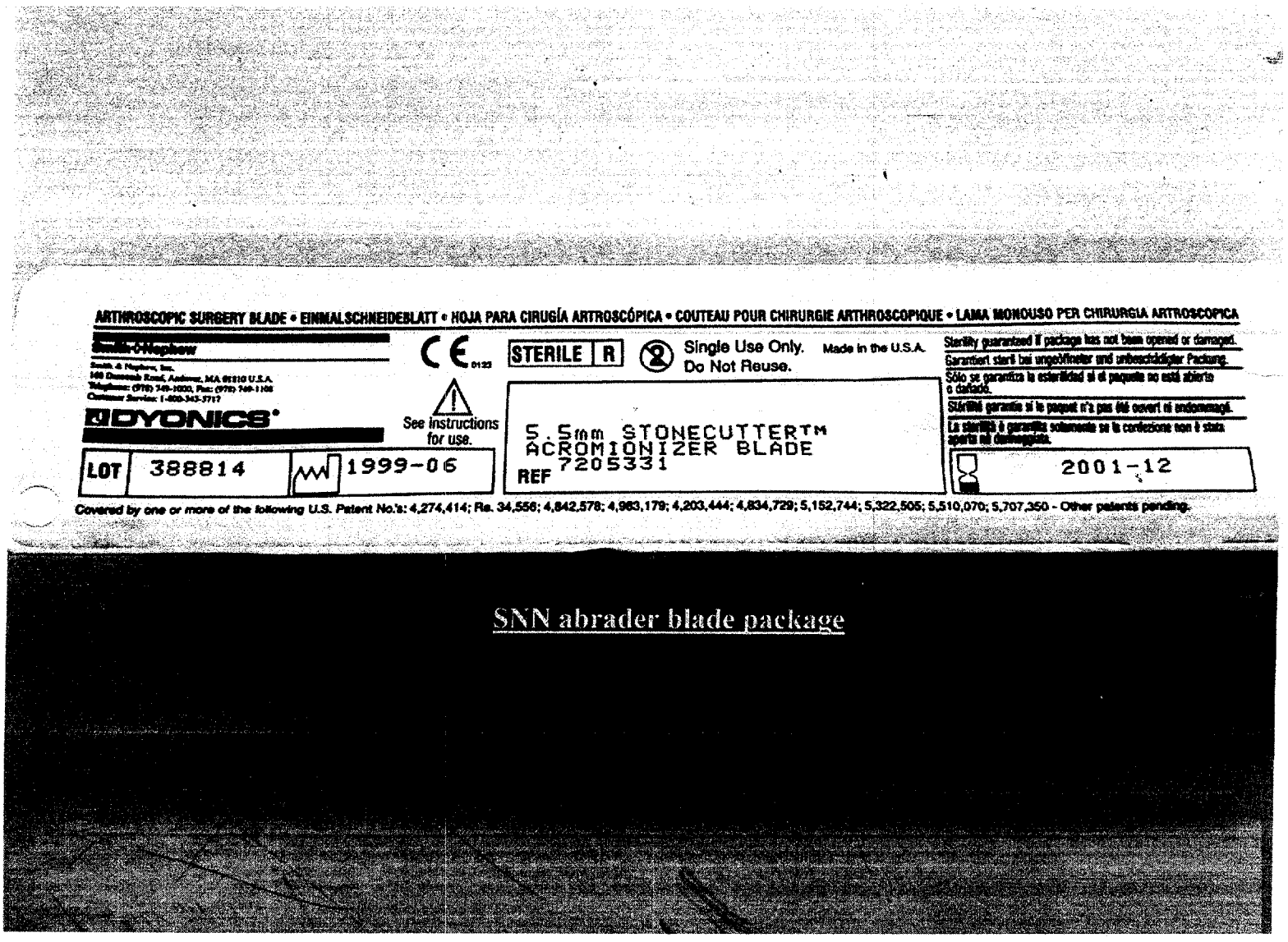
Photographs of Smith and Nephew Inc., original labels

And

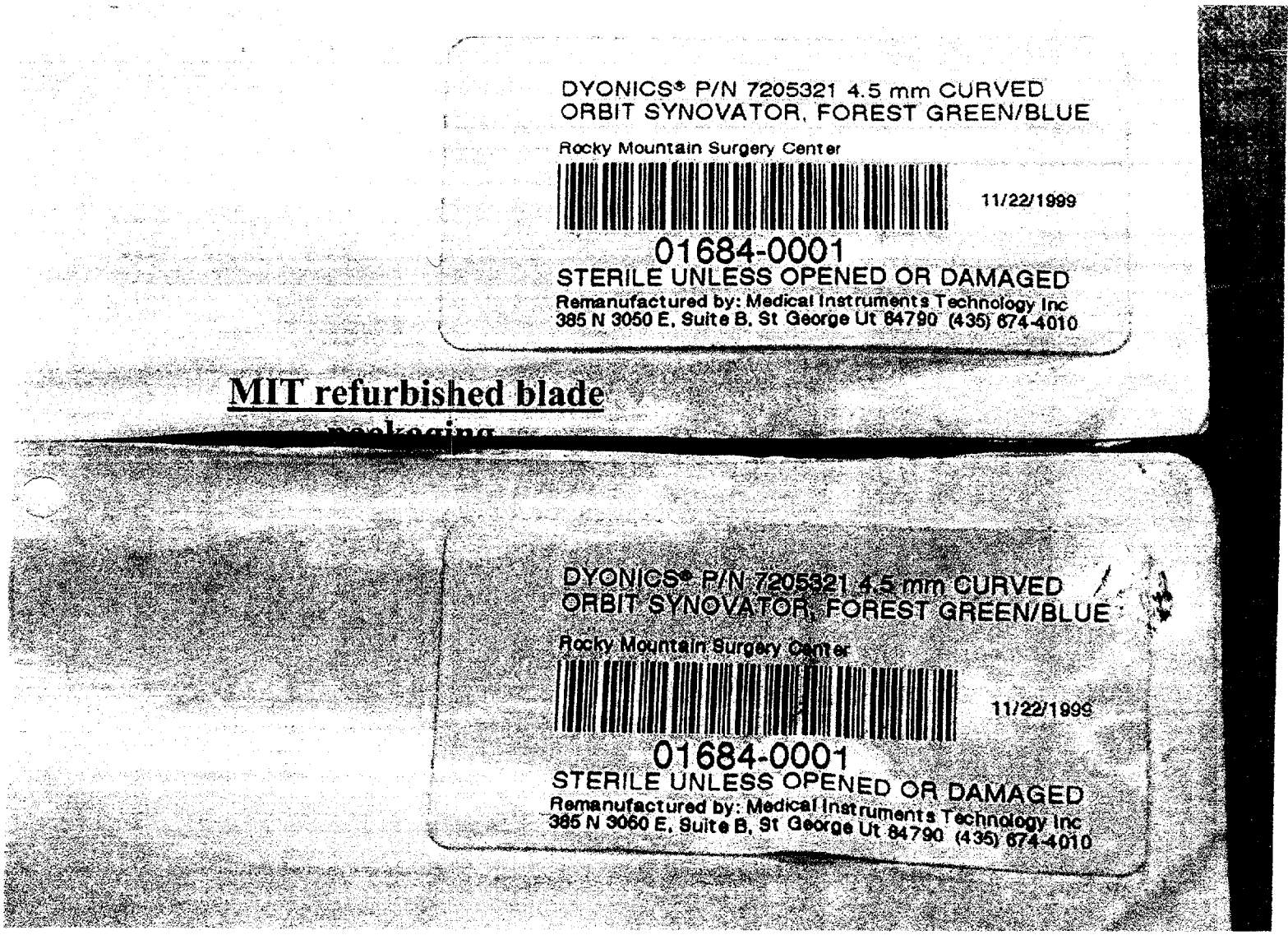
Refurbished product labels

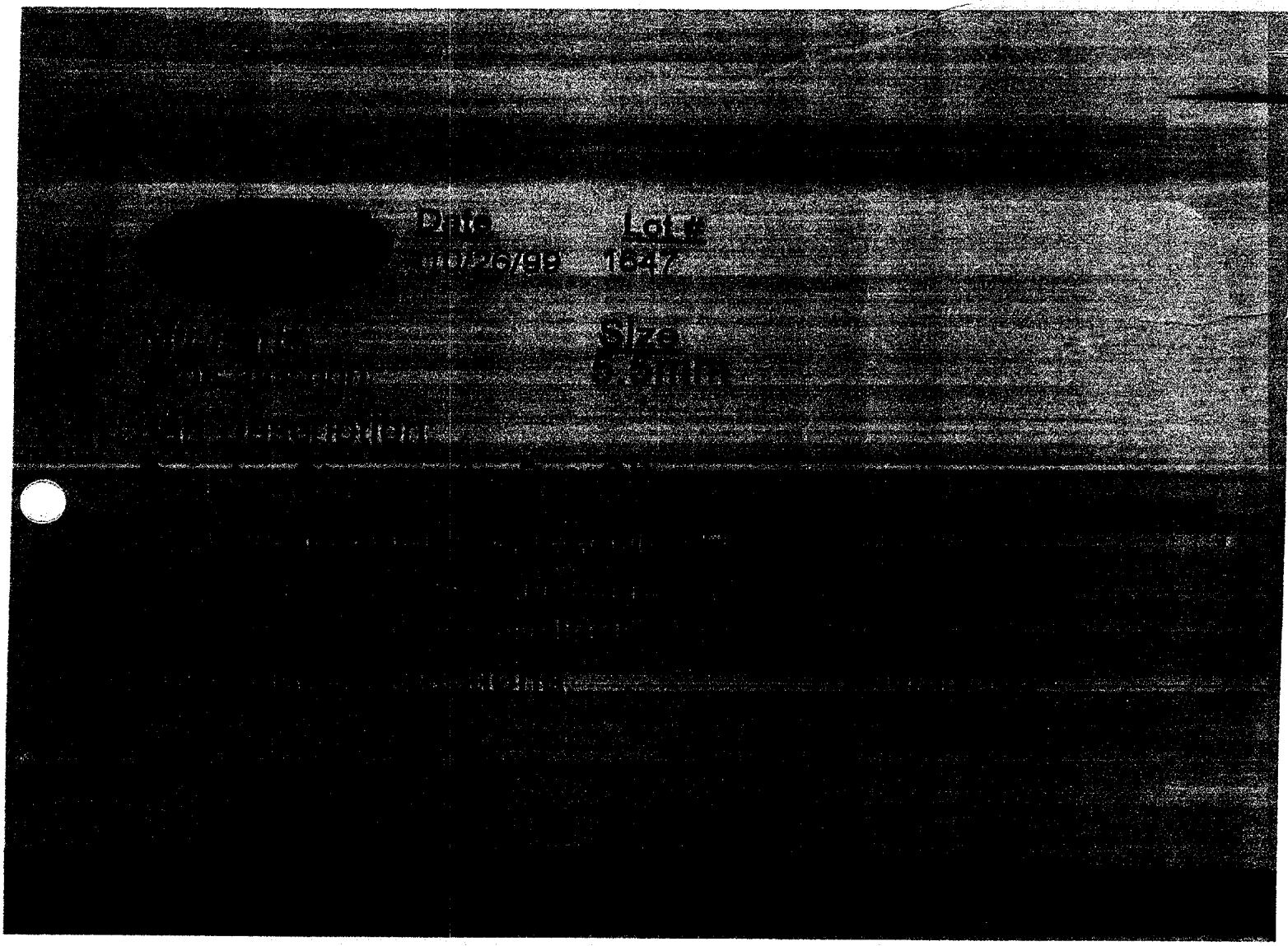


SNN Curved
Synovator Package.

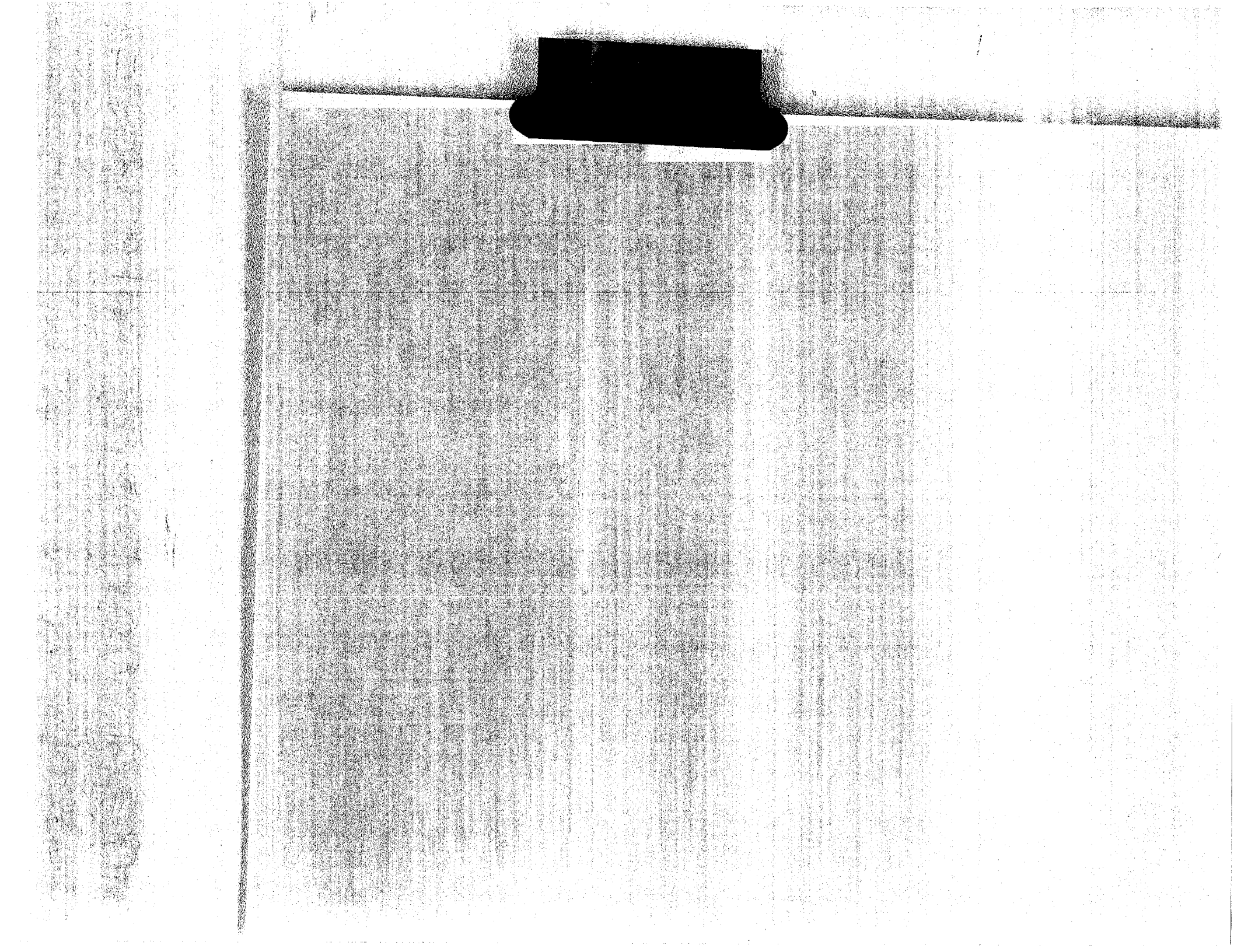


SNN abrader blade package


DYONICS® P/N 7205321 4.5 mm CURVED
ORBIT SYNOVATOR, FOREST GREEN/BLUE
Rocky Mountain Surgery Center
11/22/1999
01684-0001
STERILE UNLESS OPENED OR DAMAGED
Remanufactured by: Medical Instruments Technology Inc
385 N 3050 E, Suite B, St George Ut 84790 (435) 674-4010
MIT refurbished blade
DYONICS® P/N 7205321 4.5 mm CURVED
ORBIT SYNOVATOR, FOREST GREEN/BLUE
Rocky Mountain Surgery Center
11/22/1999
01684-0001
STERILE UNLESS OPENED OR DAMAGED
Remanufactured by: Medical Instruments Technology Inc
385 N 3060 E, Suite B, St George Ut 84790 (435) 674-4010


Lot #
1647
Size


DYONICS® P/N 4138 4.5 mm CURVED
CONCAVE SYNOVATOR,FOREST GREEN
Pocatello Regional Medical Center
1/21/2000
01897-0004
STERILE UNLESS OPENED OR DAMAGED
Remanufactured by: Medical Instruments Technology Inc
365 N 3050 E, Suite B, St George Ut 84790 (435) 674-4010
DYONICS® P/N 4138 4.5 mm CURVED
CONCAVE SYNOVATOR,FOREST GREEN
Pocatello Regional Medical Center
1/21/2000
01897-0004
STERILE UNLESS OPENED OR DAMAGED
Remanufactured by: Medical Instruments Technology Inc
365 N 3050 E, Suite B, St George Ut 84790 (435) 674-4010
Refurbished blade
packaging, labels
lifting.
DYONICS® P/N 4138 4.5 mm CURVED
CONCAVE SYNOVATOR,FOREST GREEN
Pocatello Regional Medical Center
1/21/2000
01897-0004
STERILE UNLESS OPENED OR DAMAGED
Remanufactured by: Medical Instruments Technology Inc
365 N 3050 E, Suite B, St George Ut 84790 (435) 674-4010

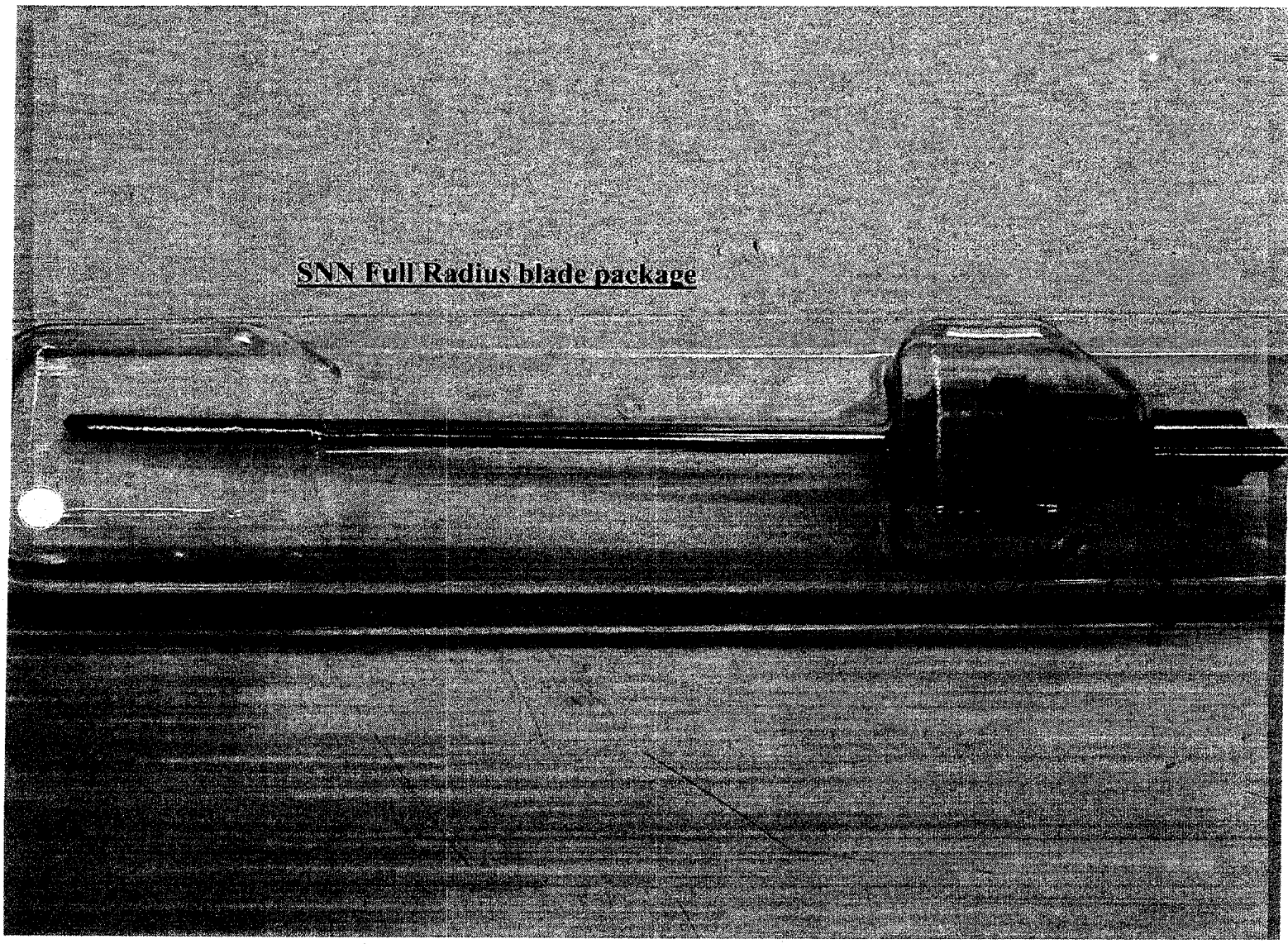


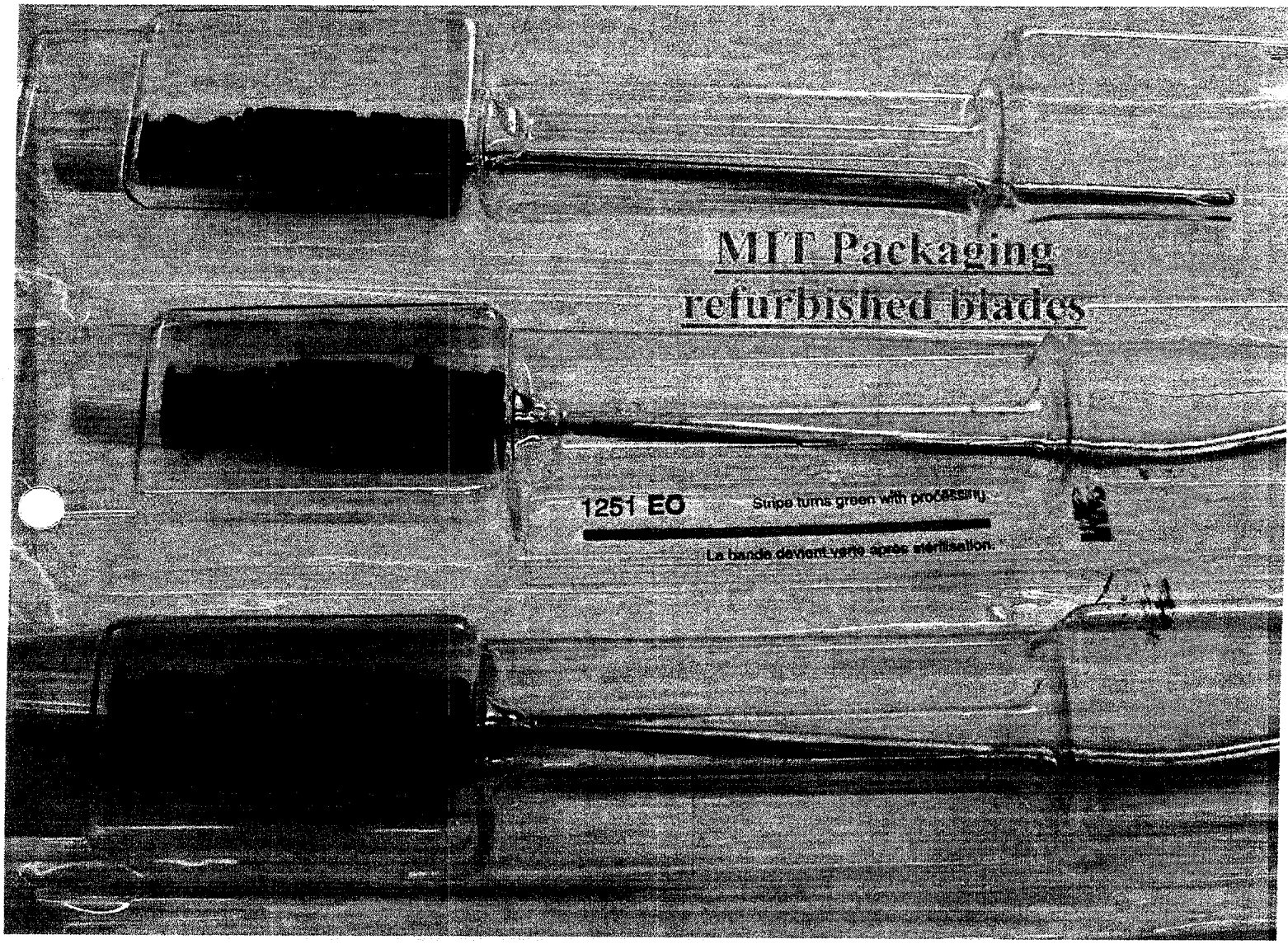
ATTACHMENT II

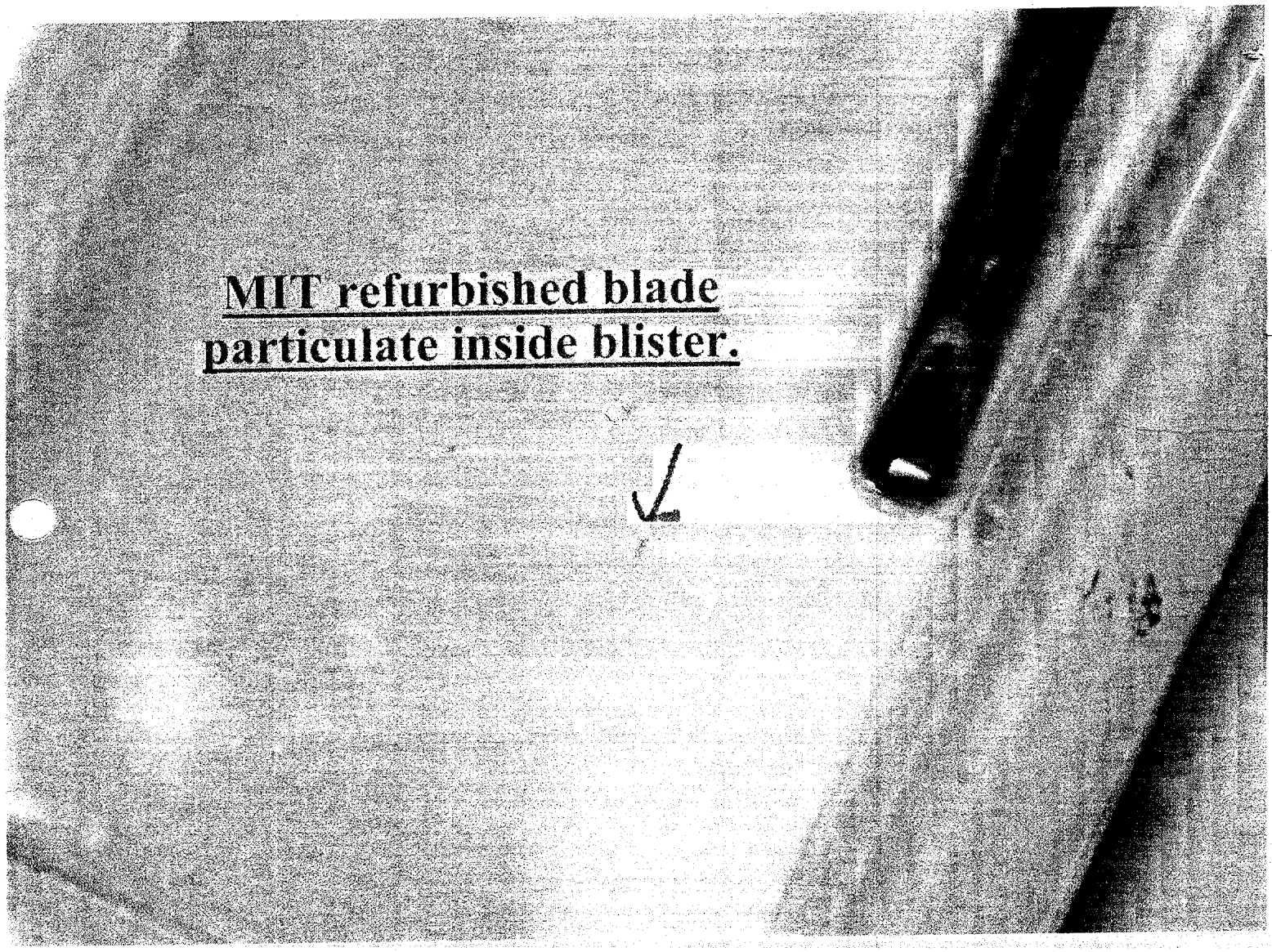
Photographs of Smith and Nephew Inc, packaged blades

And

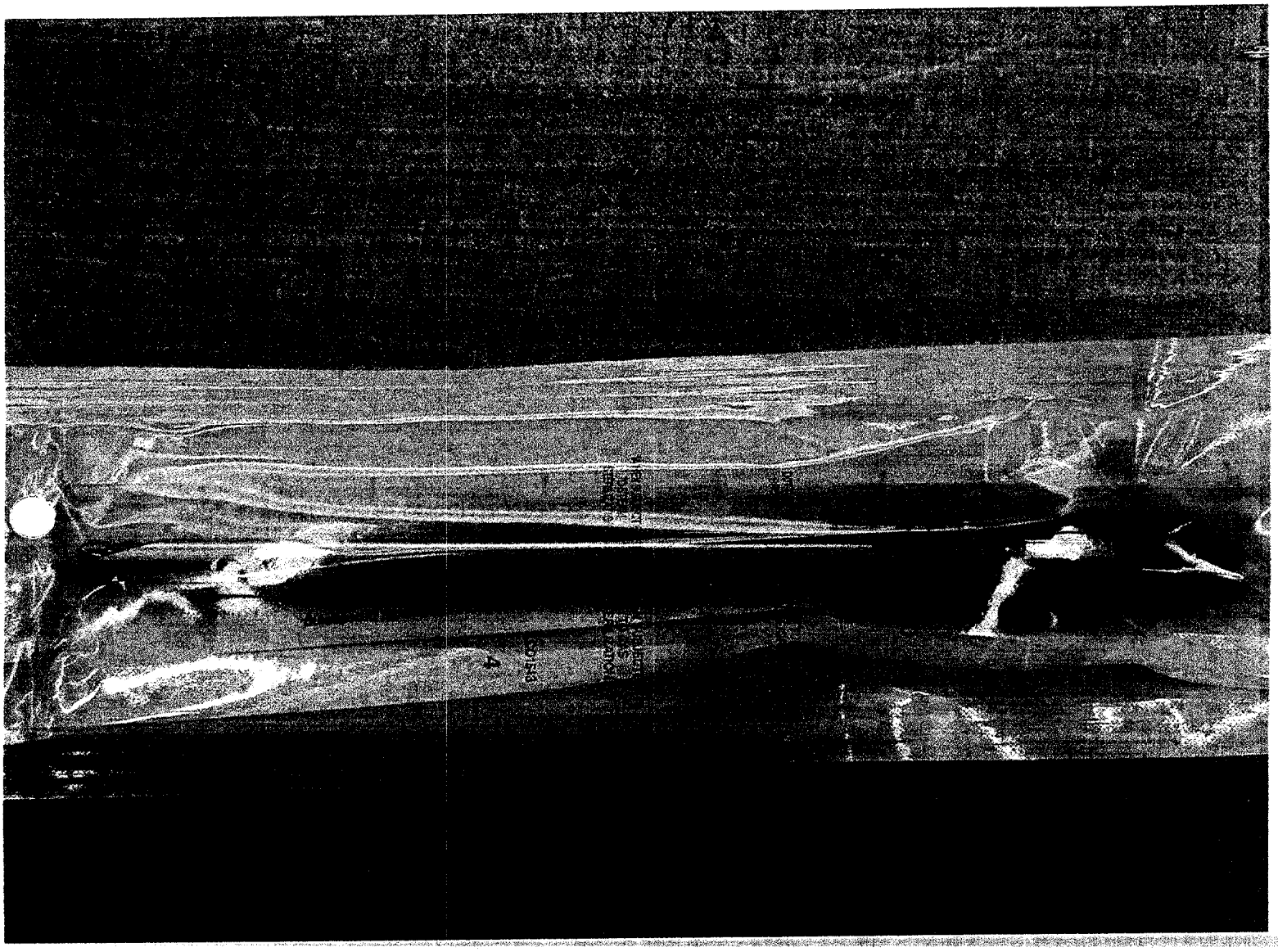
Refurbished packaged blades


SNN Full Radius blade package


MIT Packaging
refurbished blades
1251 EO
Stripe turns green with processing
La bande devient verte après stérilisation.


MIT refurbished blade
particulate inside blister.


MIT refurbished blade packaging
particulate in package

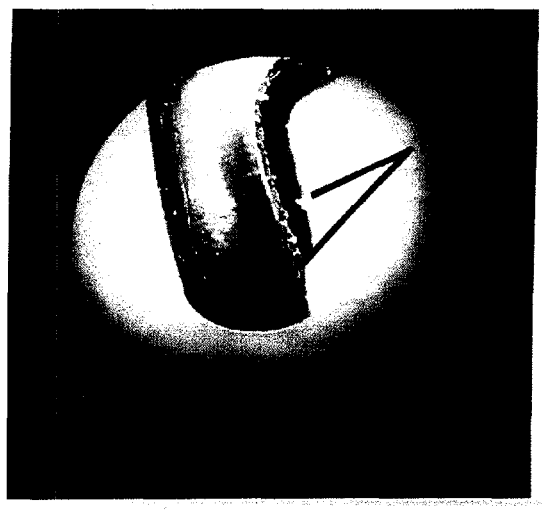


ATTACHMENT III

ATTACHMENT III

Photographs of new and refurbished blades

Incisor, 4.5mm inner blade, edgeform of new blade.

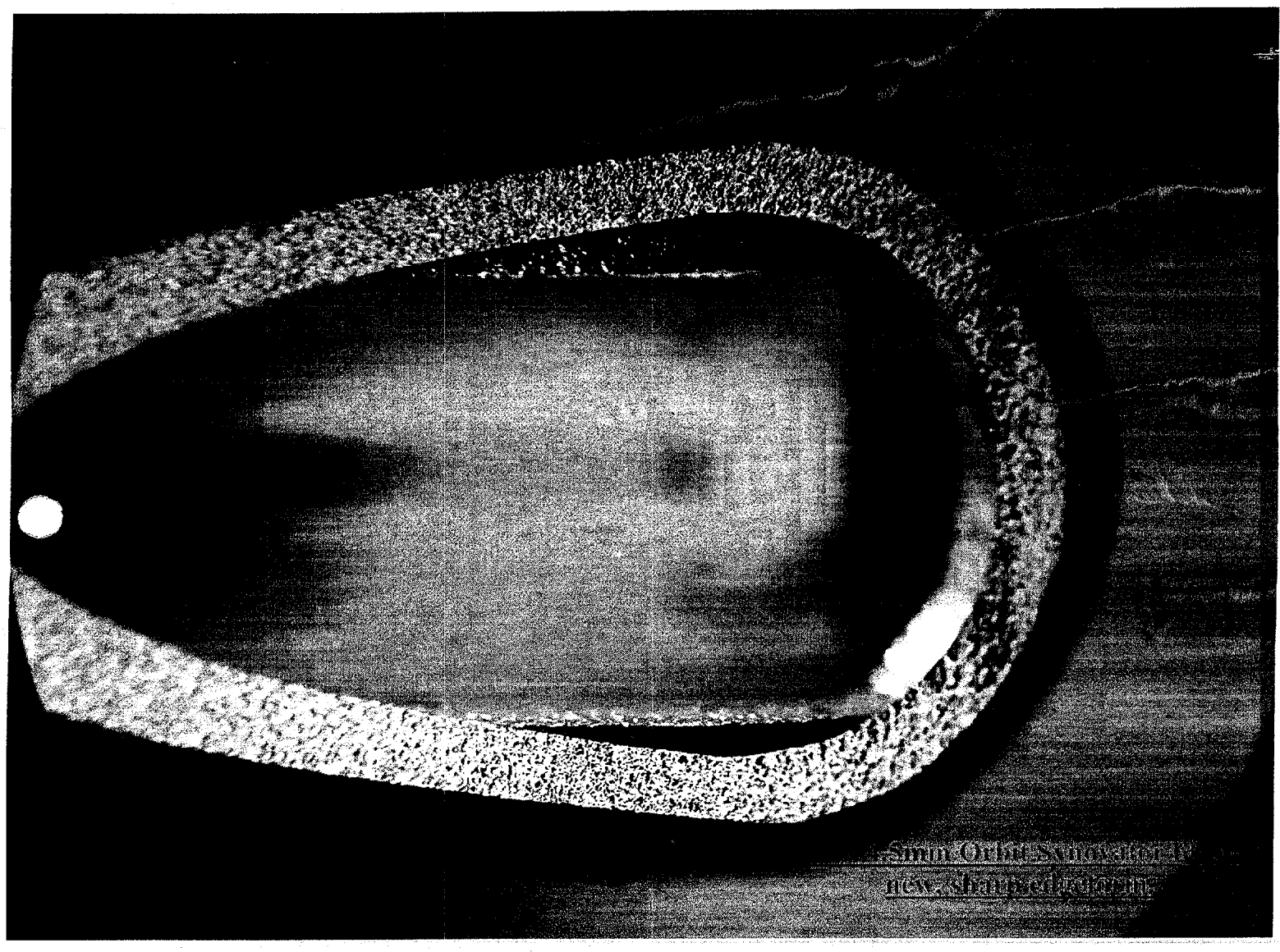


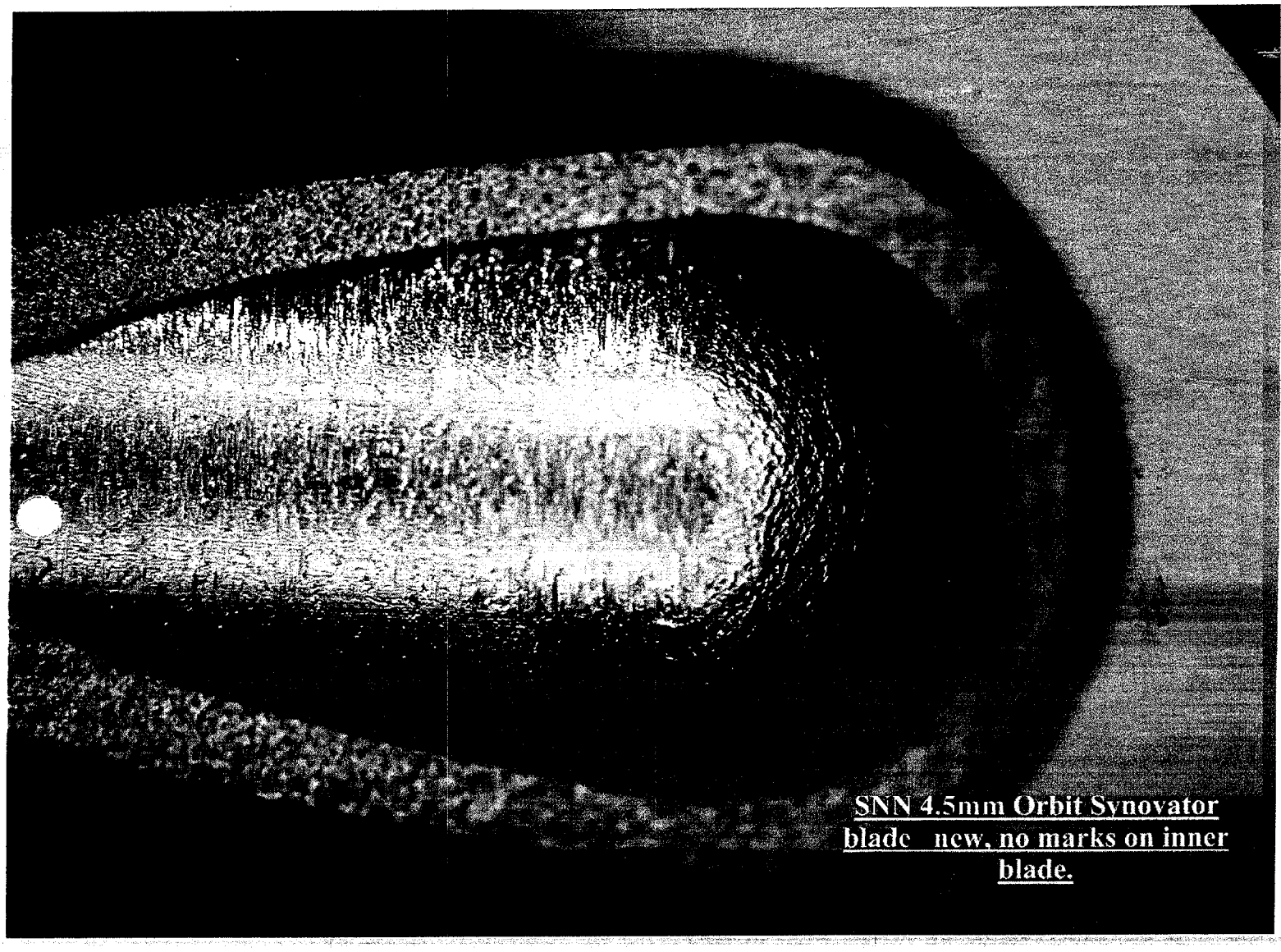
Refurbished Cutter, 3.5mm inner blade showing rough, ground cutting edges and loose metal fragments.

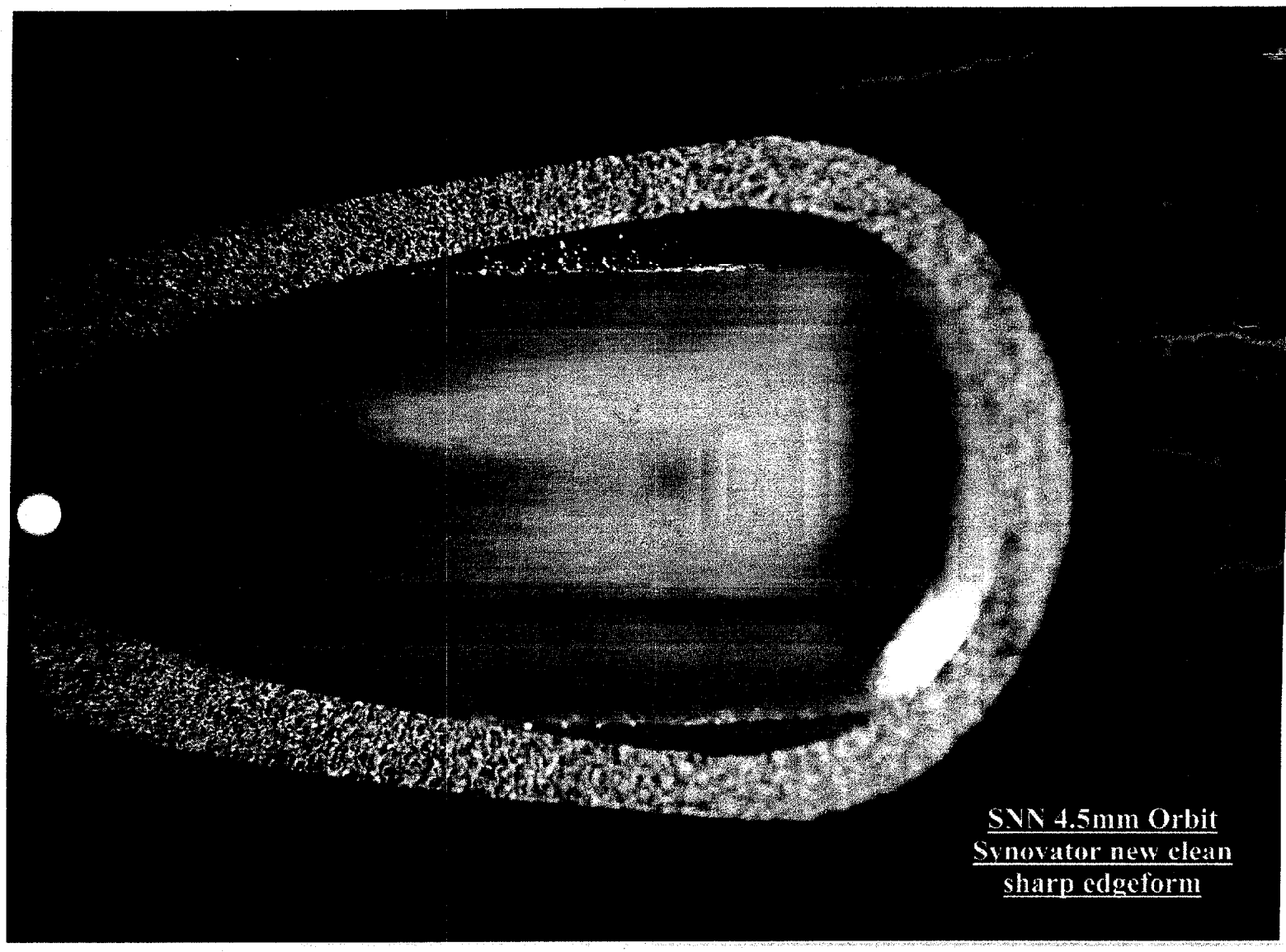
*SEM Micrograph of an **unused** 5.5 Full Radius Disposable Blade showing sharp edge*

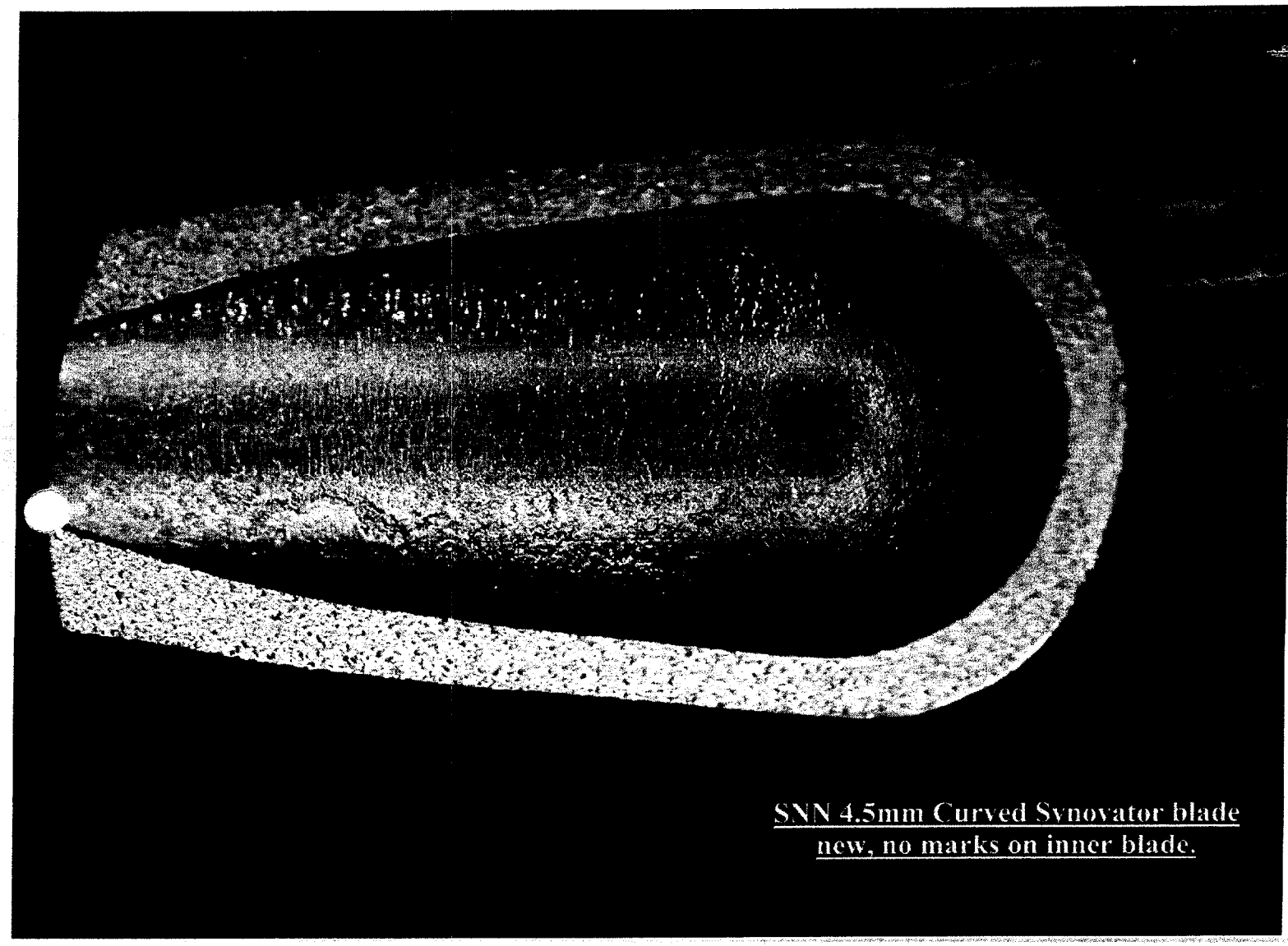
*SEM Micrograph of a **refurbished** 5.5 Full Radius Disposable Blade showing dulled edge*

Refurbished Incisor, 4.5mm, edgeform of inner blade showing loose metal fillings.

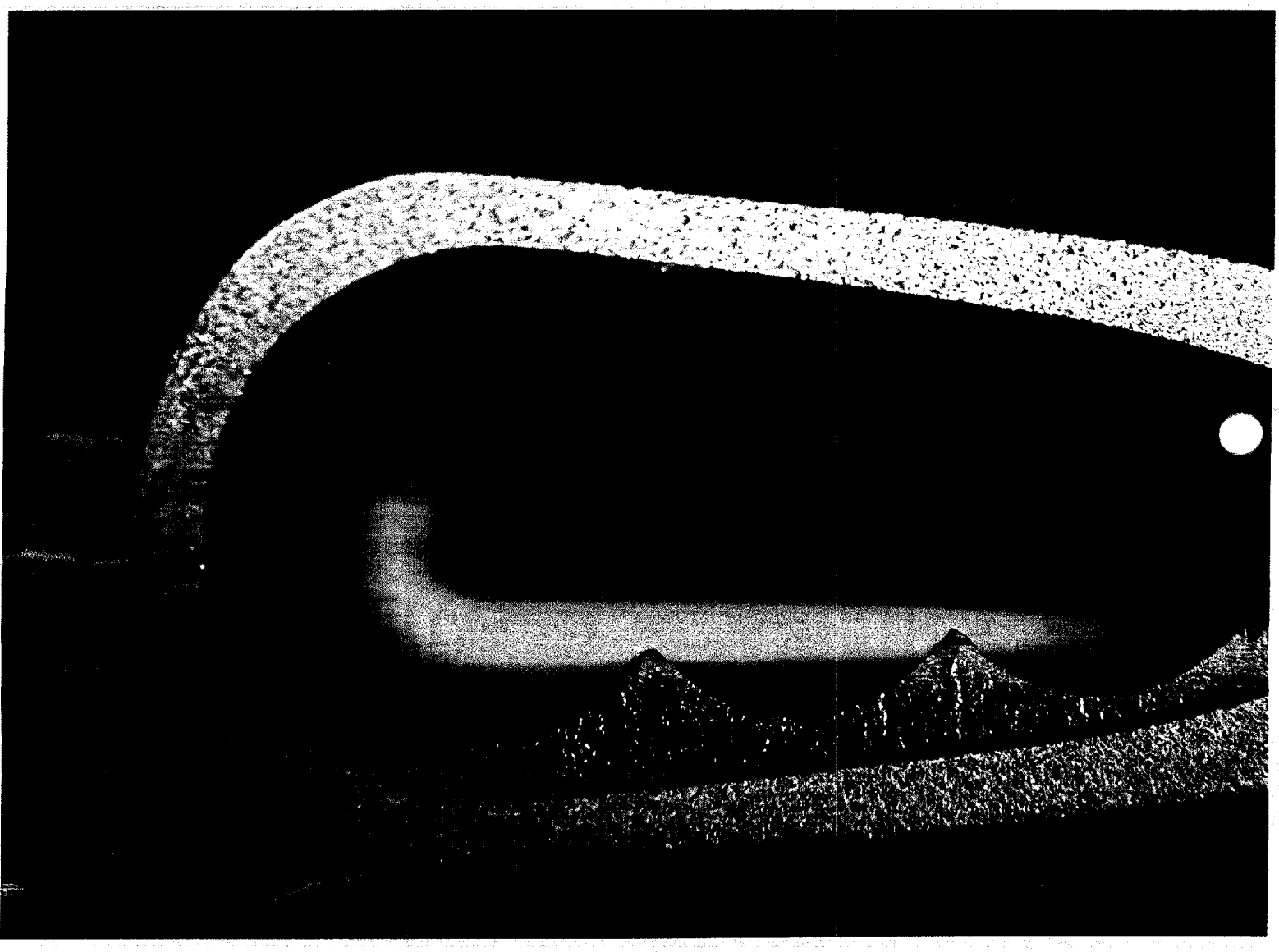


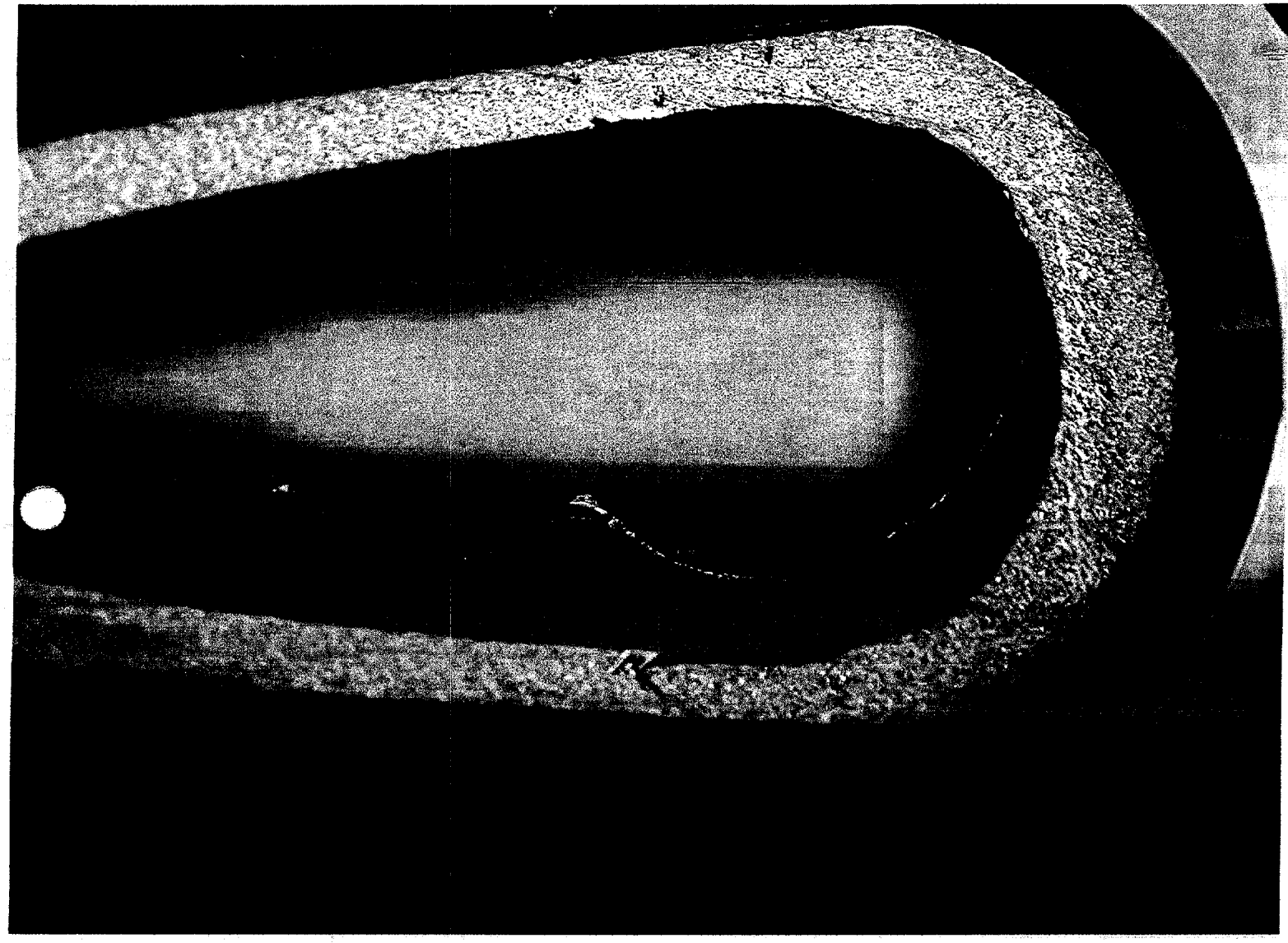

SNN 4.5mm Orbit Synovator
blade new, no marks on inner
blade.

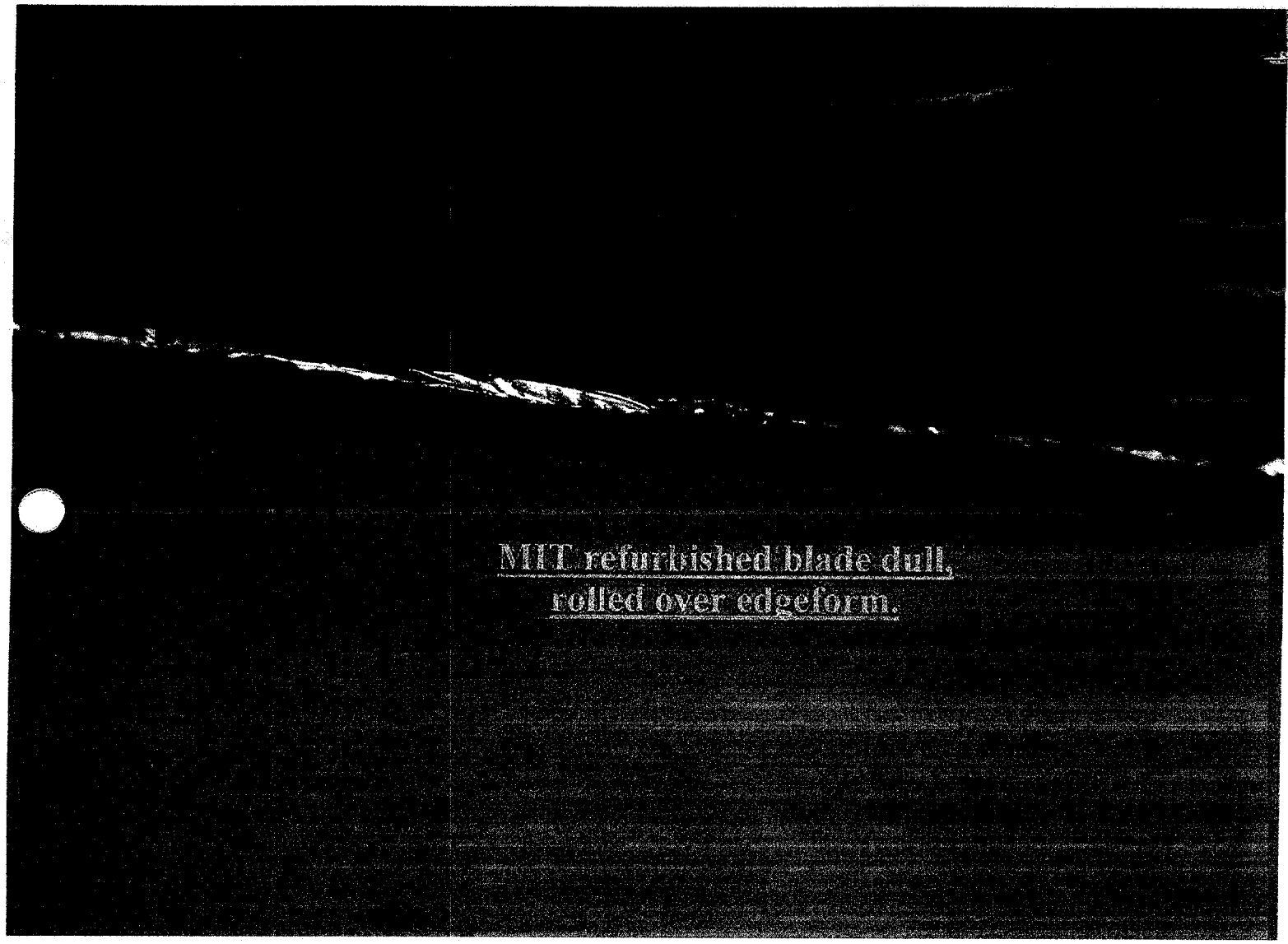

SNN 4.5mm Orbit
Synovator new clean
sharp edgeform

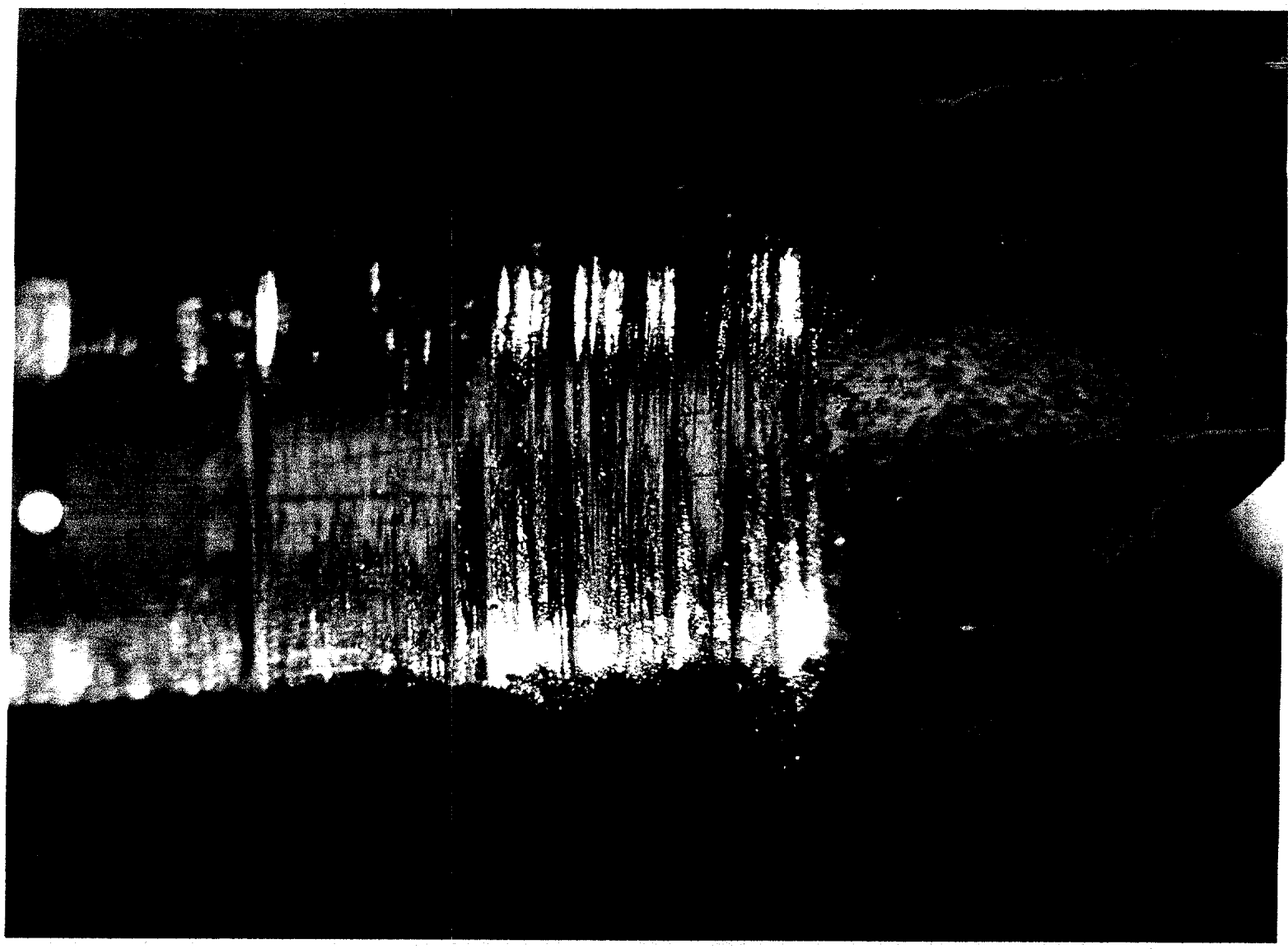


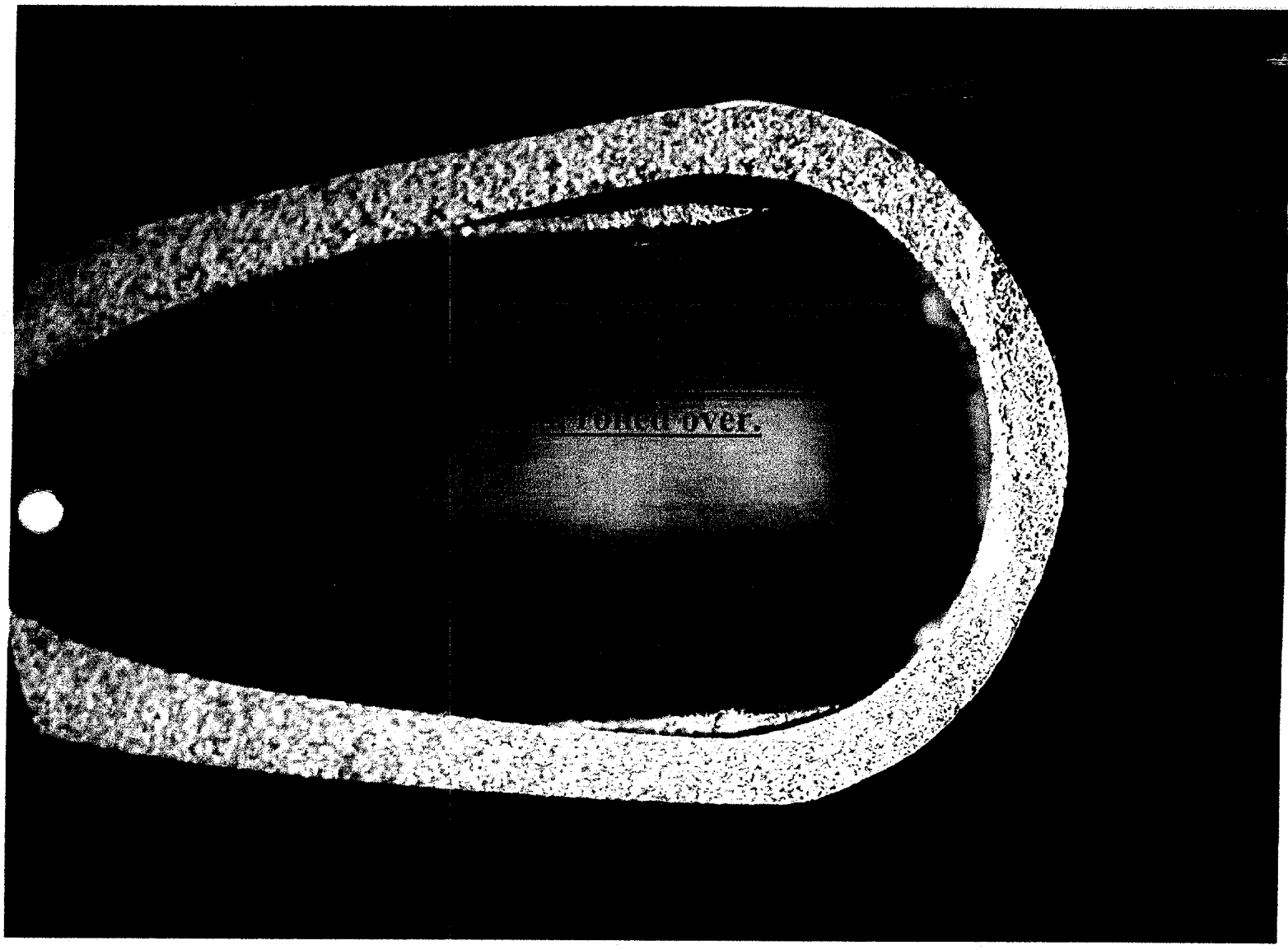
SNN 4.5mm Curved Synovator blade
new, no marks on inner blade.



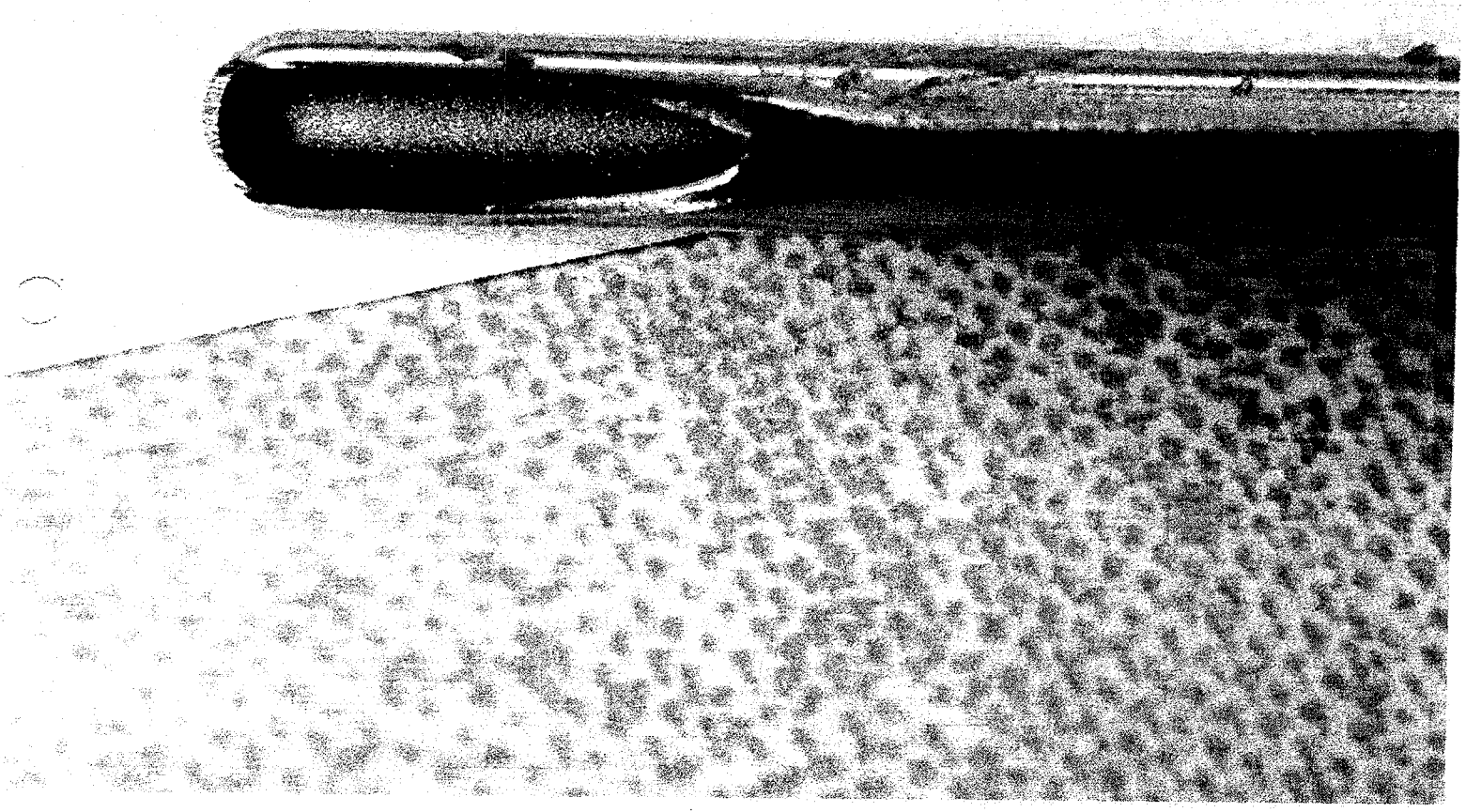


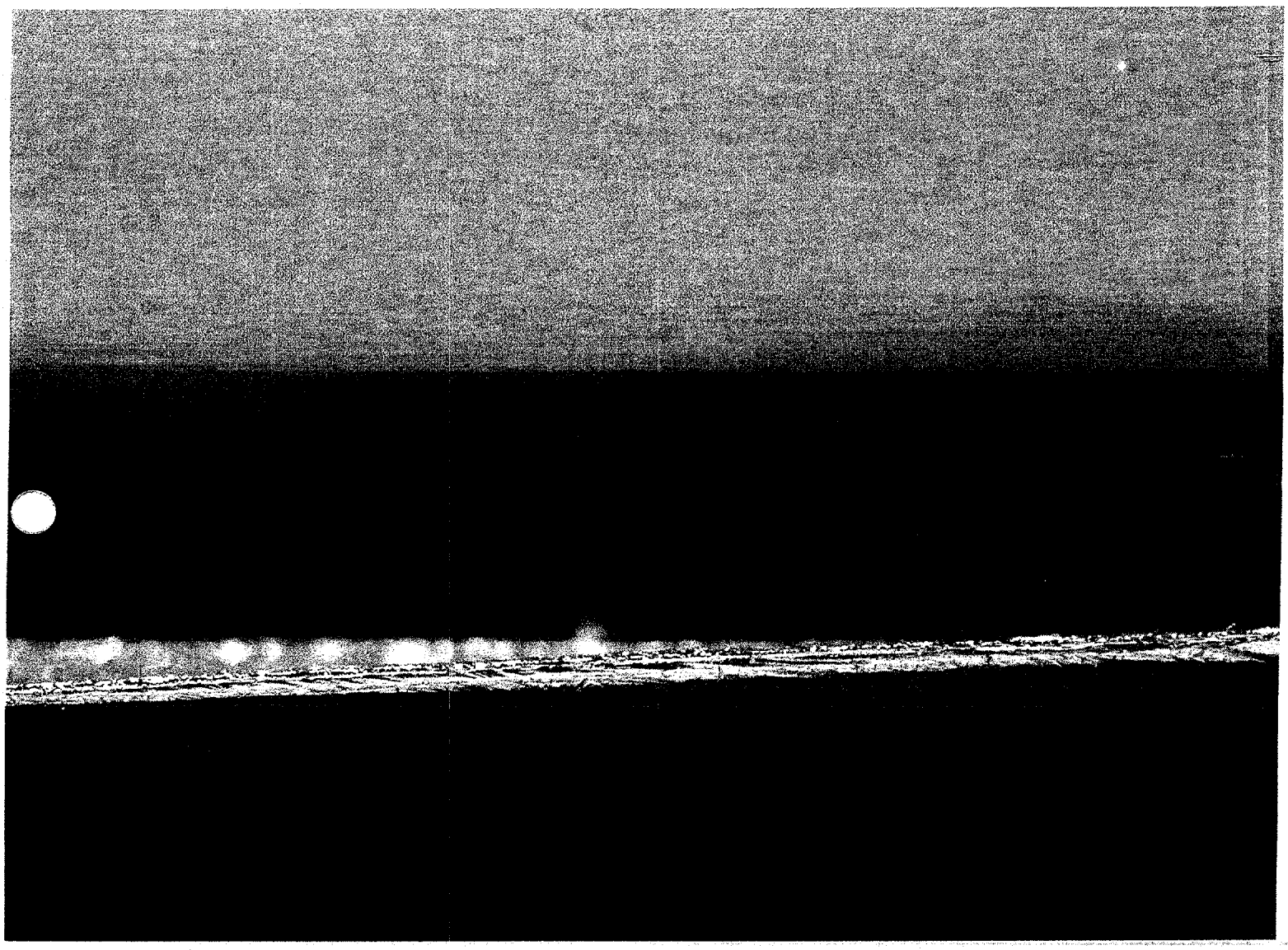

MIT refurbished blade dull,
rolled over edgeform.

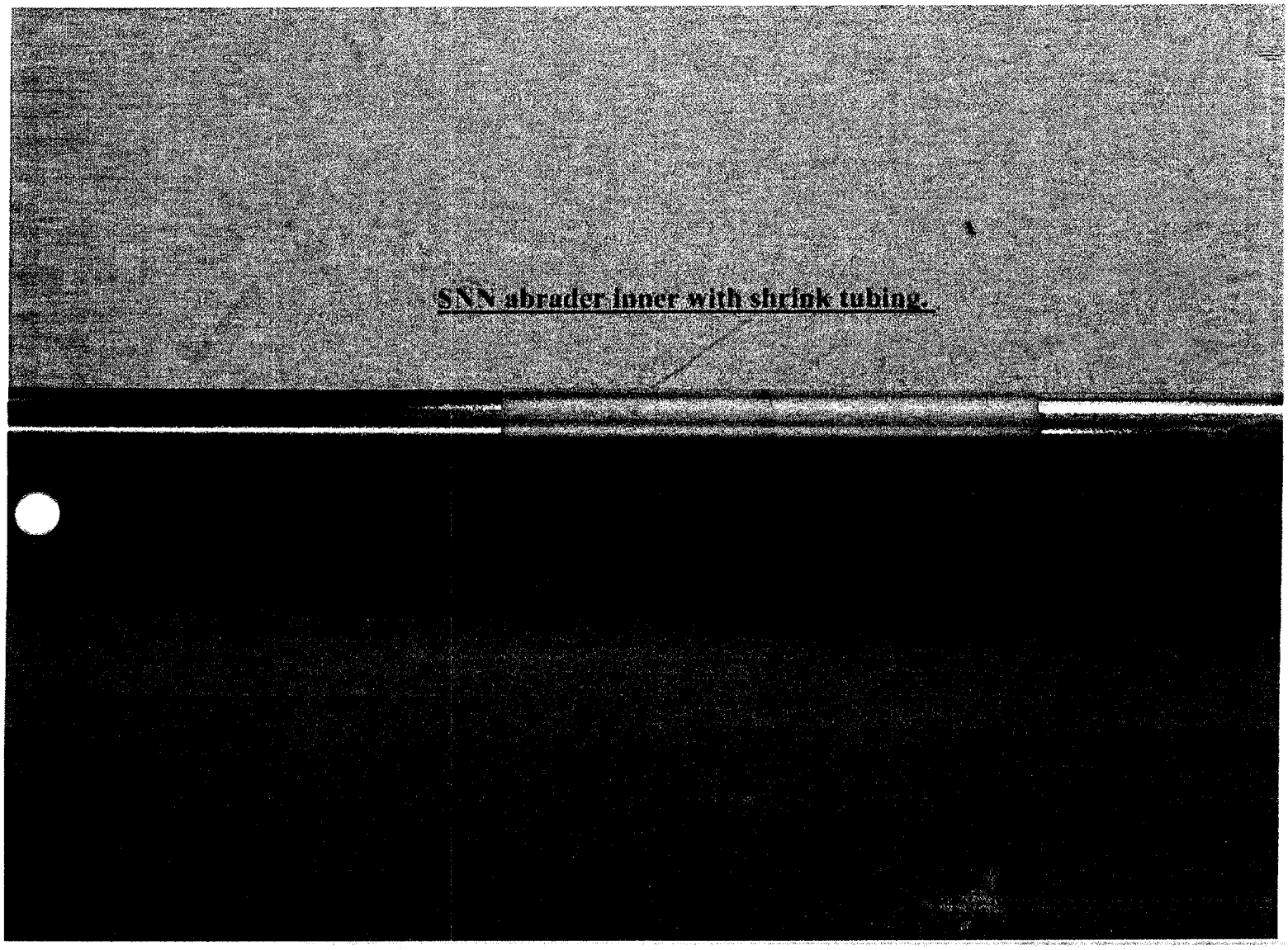



Bonnet over.

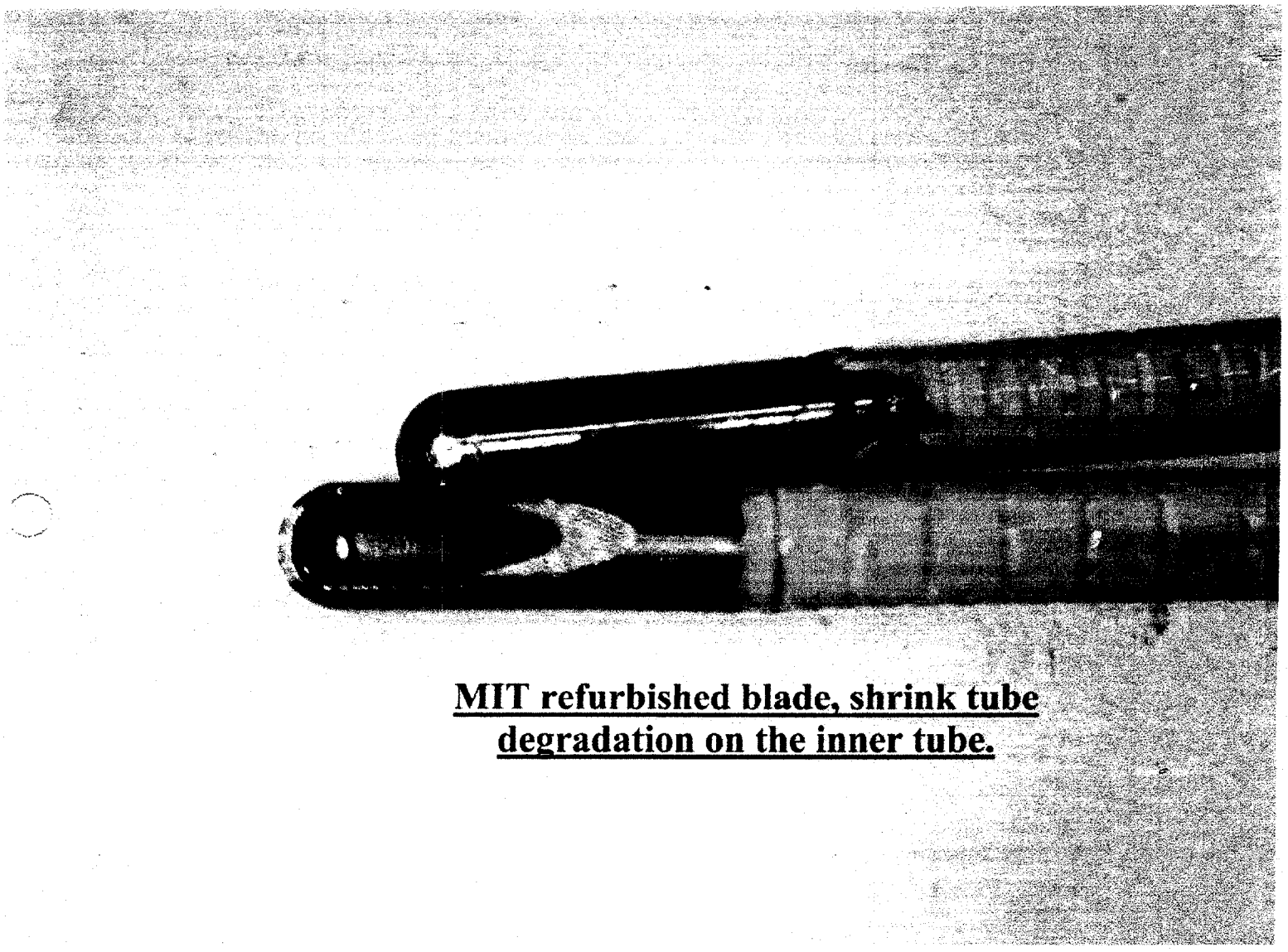
Inner blade has been buffed, polished, waxy build up on surface.



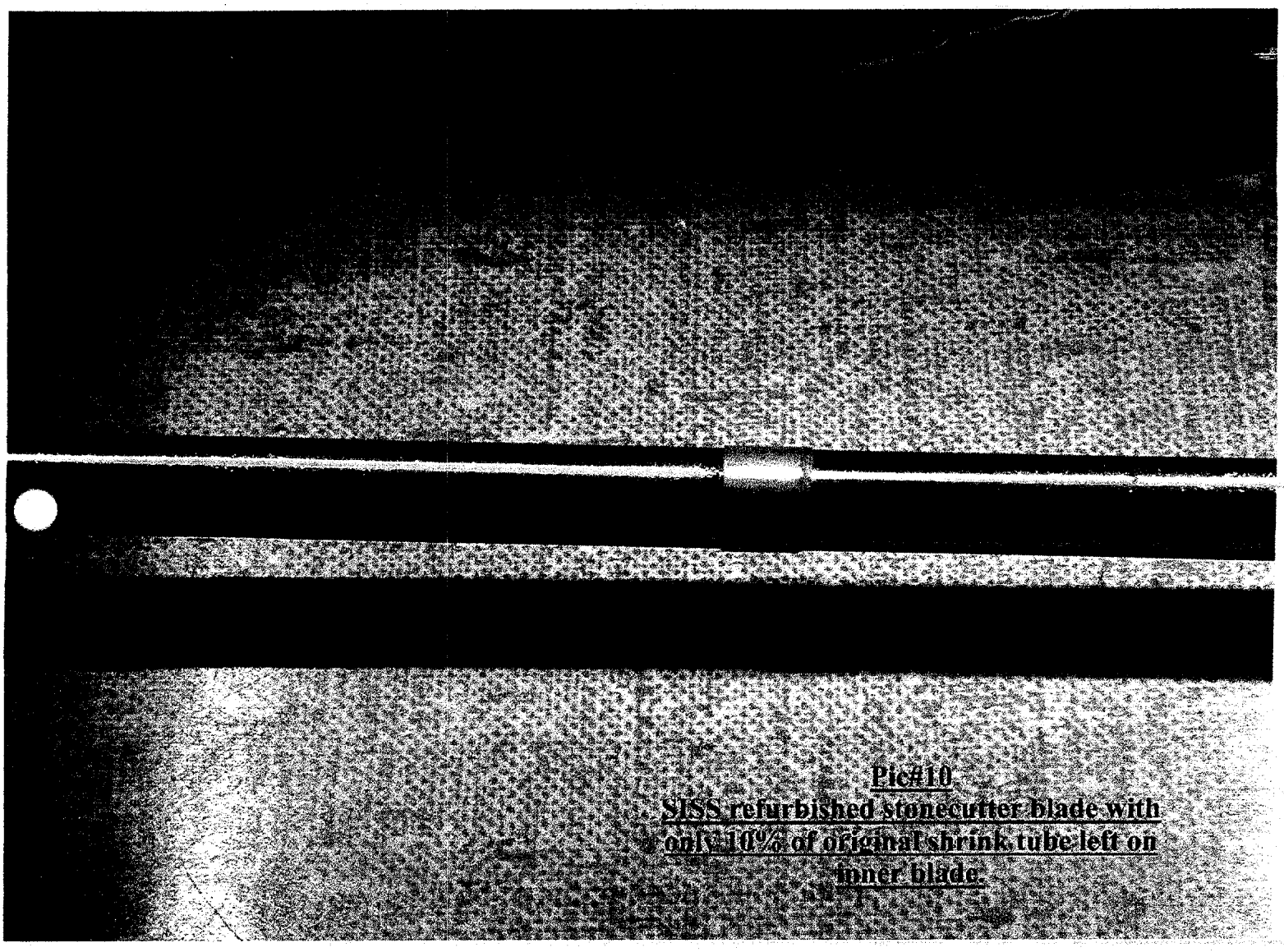




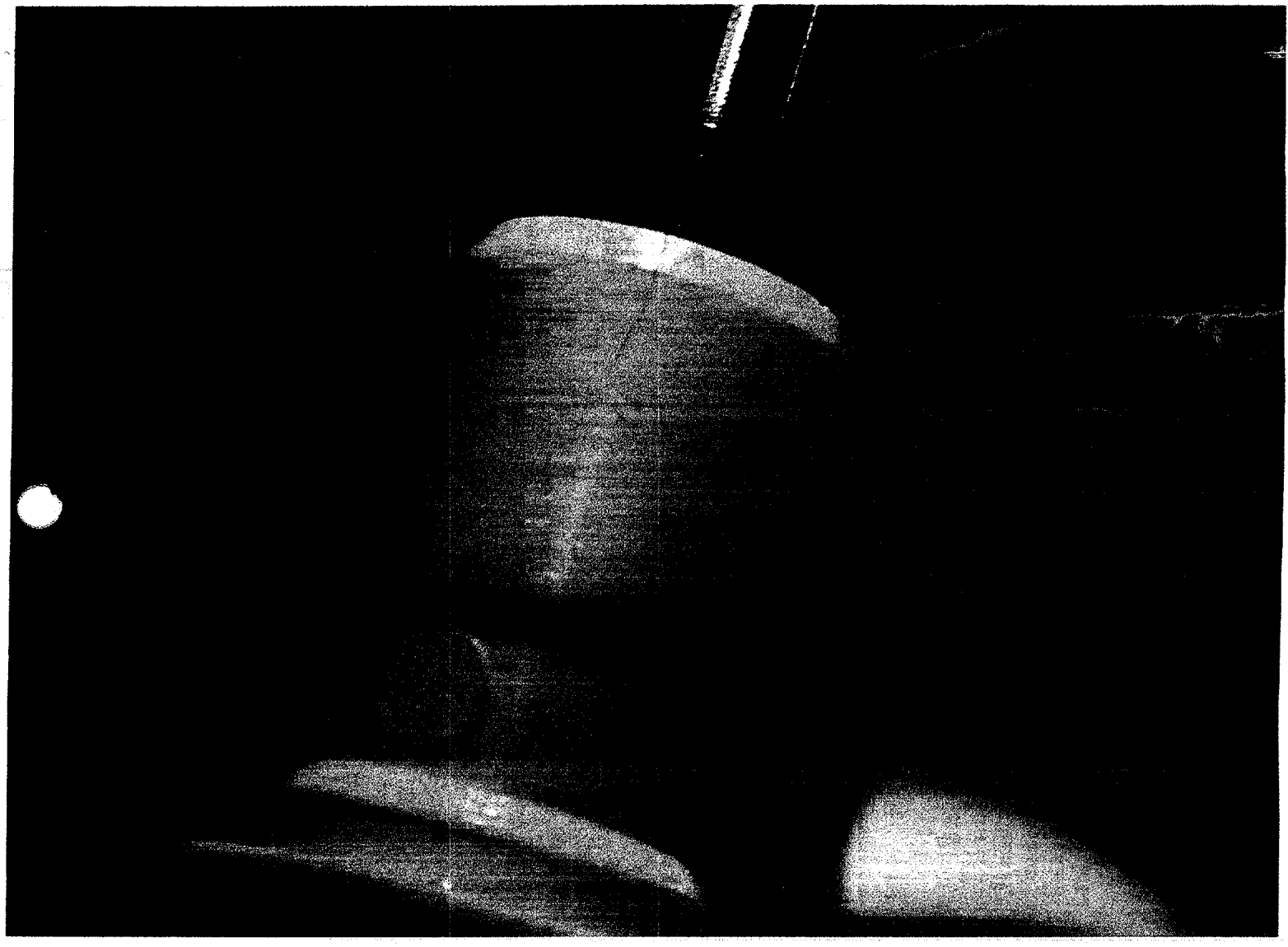
SNN sbrader inner with shrink tubing.

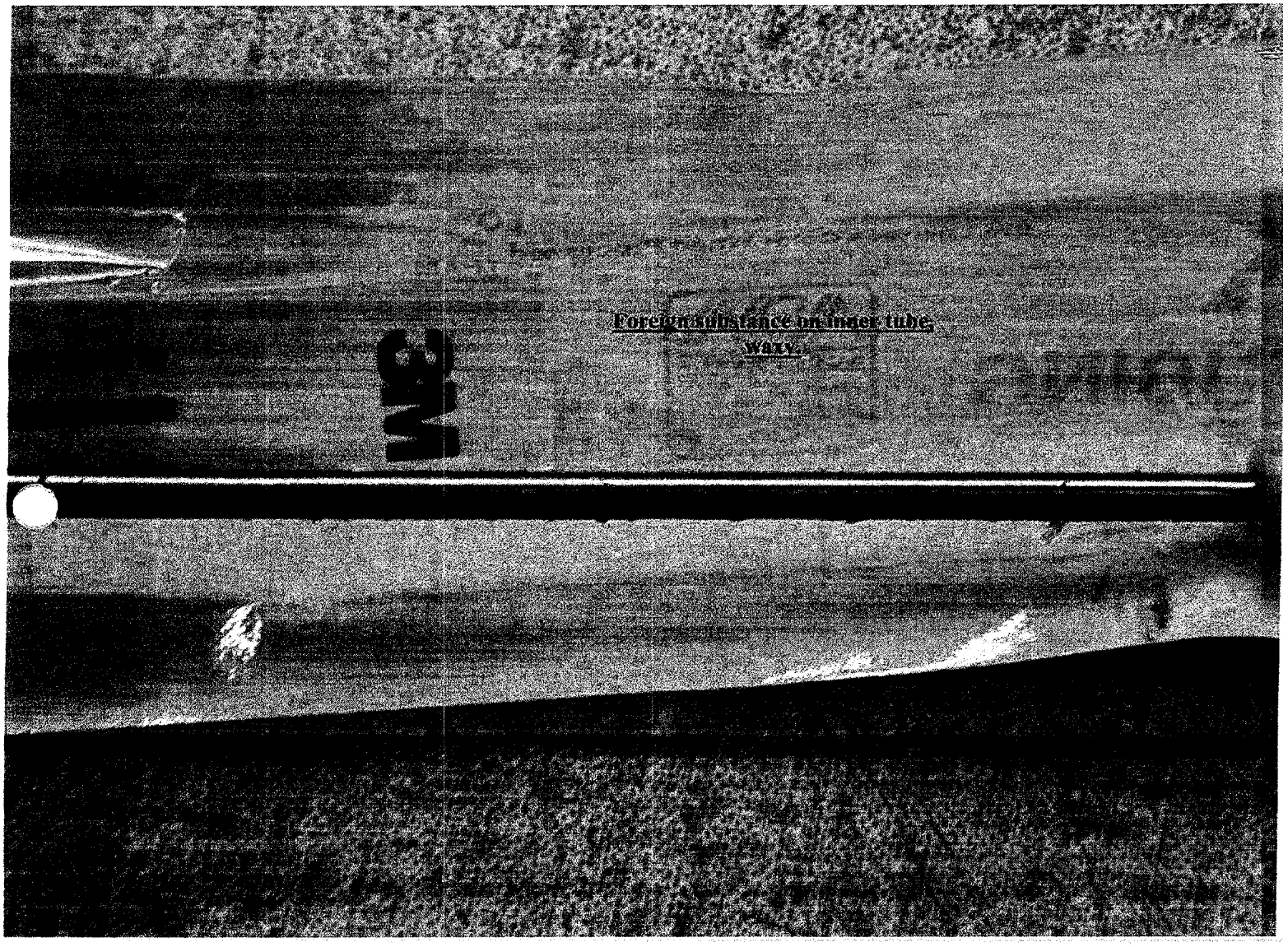


MIT refurbished blade, shrink tube degradation on the inner tube.



Pic#10
SISS refurbished stonecutter blade with only 10% of orighal shrink tube left on inner blade.



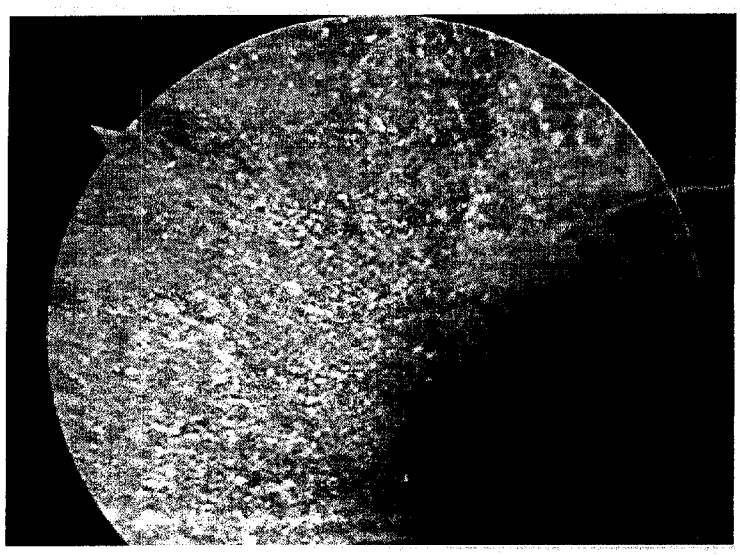


Foreign substance on inner tube, waxy.

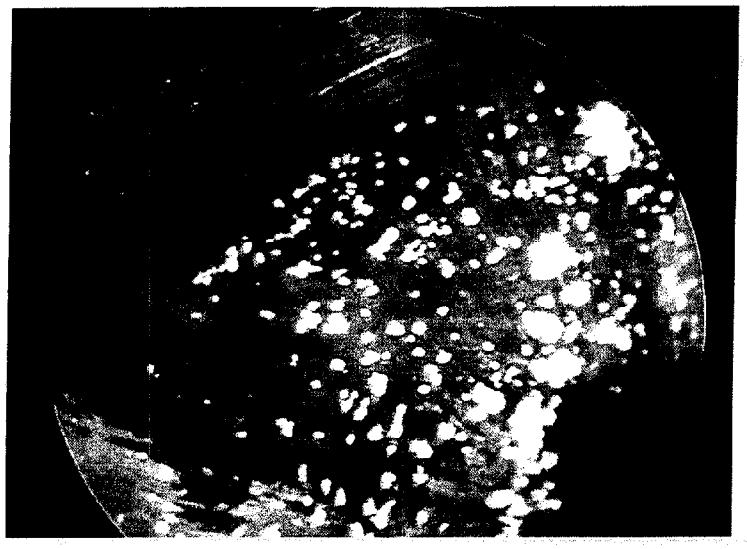
[redacted]

ATTACHMENT IV

Photographs of refurbished blades, which were not adequately cleaned

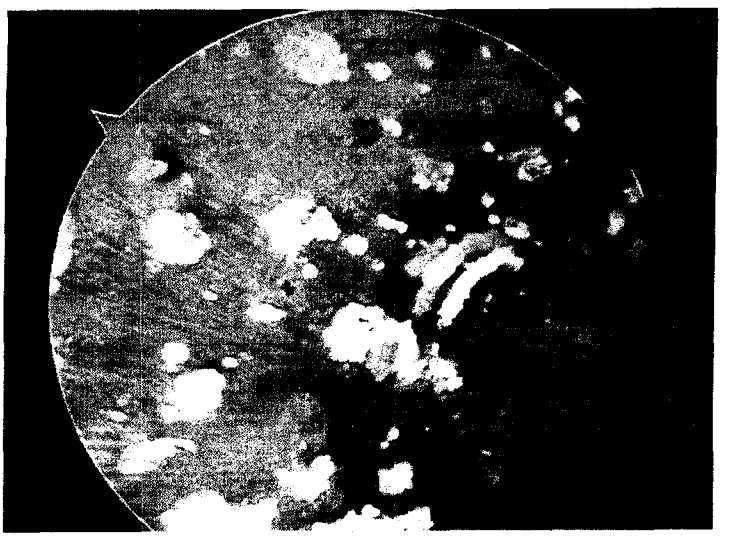


Incisor, 4.5mm, inner blade lumen of ***new*** *blade.*

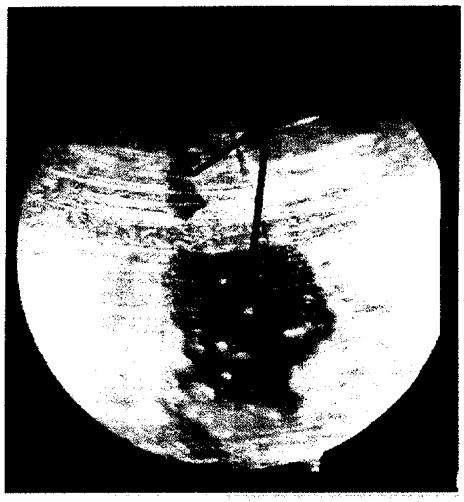


Refurbished TurboWhisker, 4.5mm, inner blade showing radial wear marks, loose particulate matter and deposits consistent with dried blood.

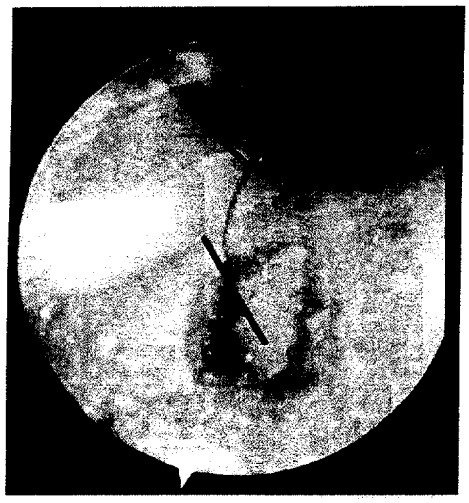
Refurbished TurboWhisker, 4.5mm inner blade lumen showing deposits consistent with dried blood.



Refurbished Incisor, 4.5mm inner blade lumen showing loose particulate matter and deposits consistent with dried blood.

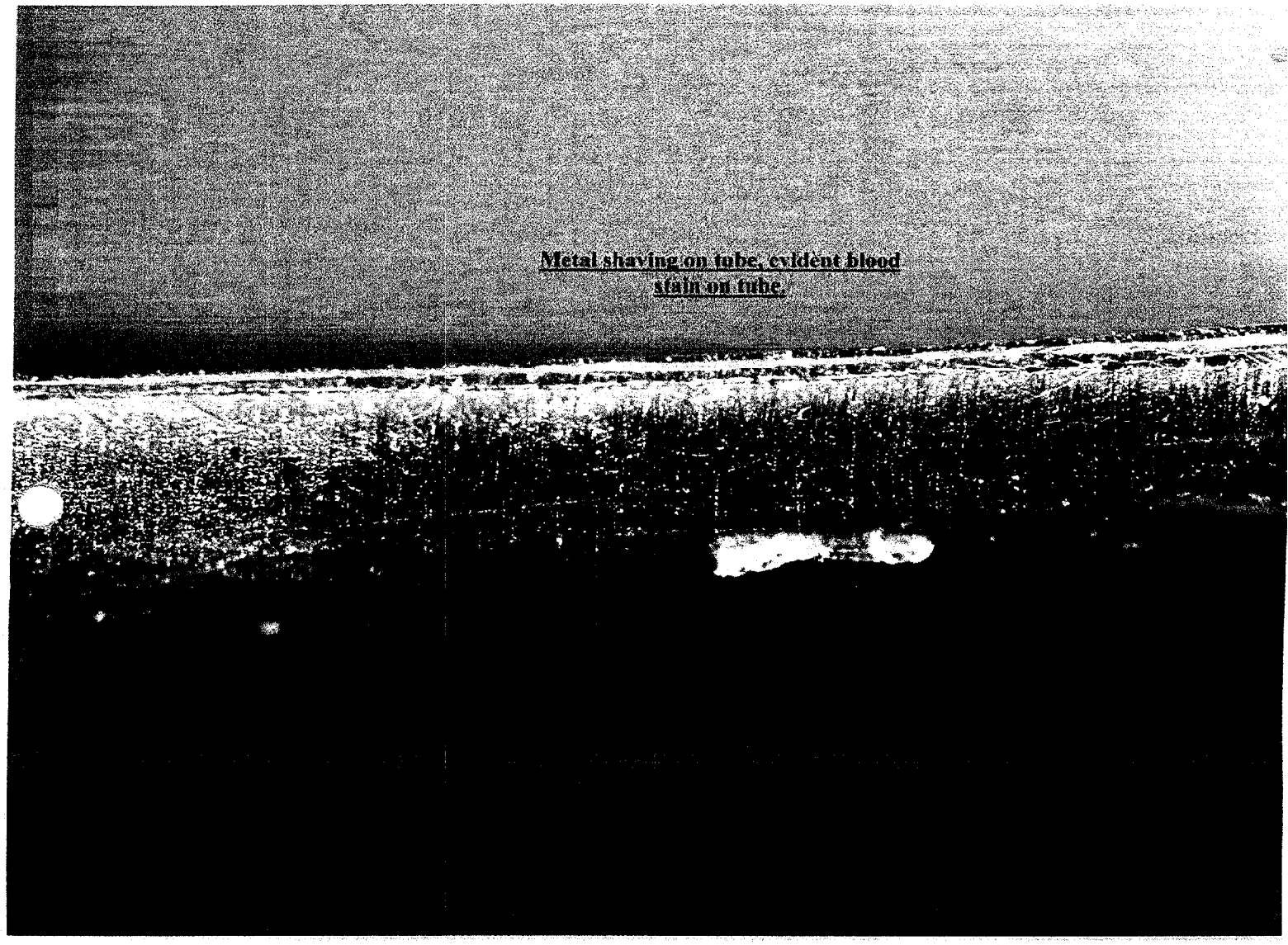


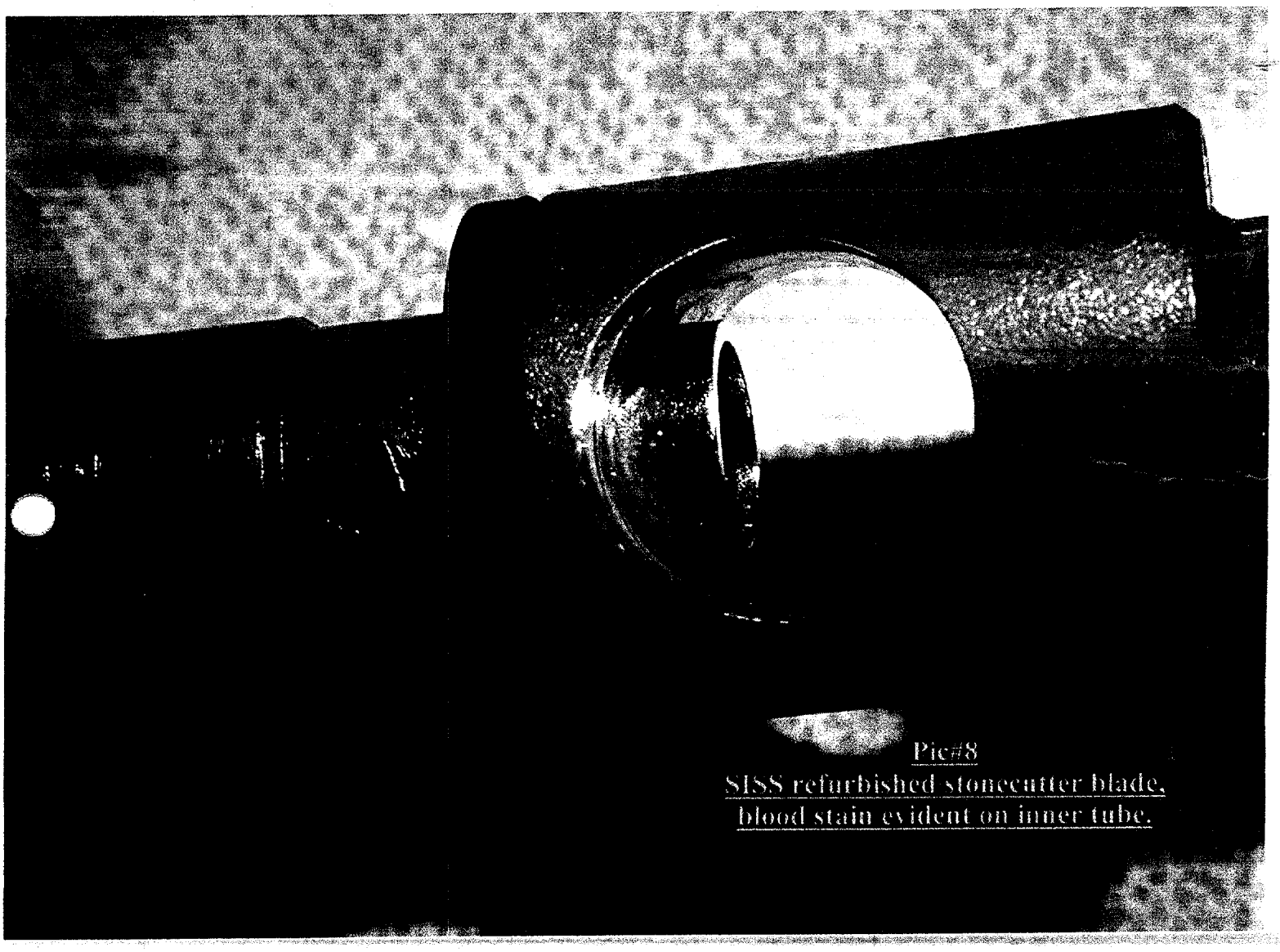
Refurbished TurboWhisker®, 4.5mm, outer blade showing deposits consistent with dried blood.



Refurbished Cutter, 3.5mm, inner blade lumen showing loose particulates and deposits consistent with dried blood.

[redacted]


Metal shaving on tube, evident blood
stain on tube.

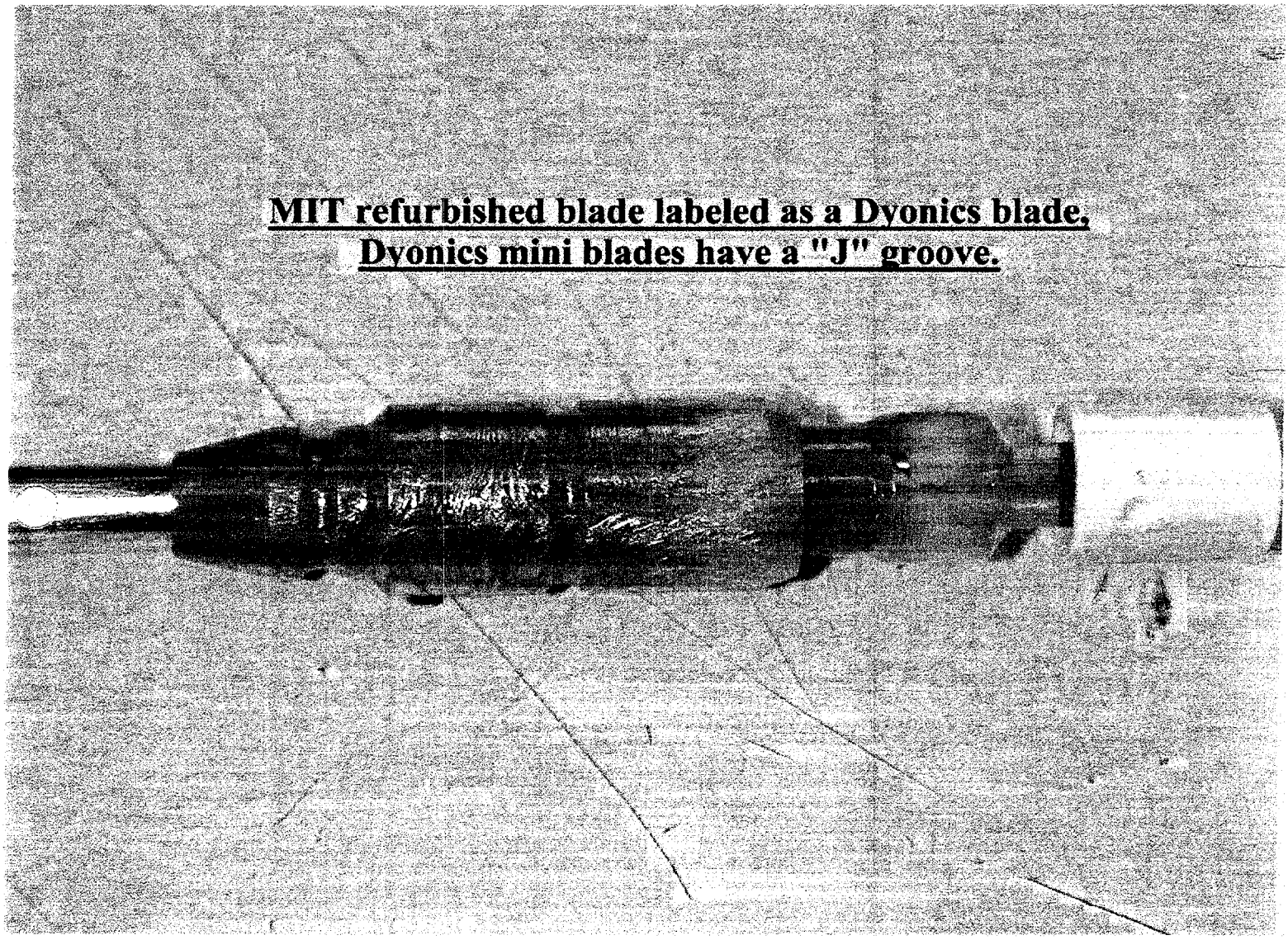


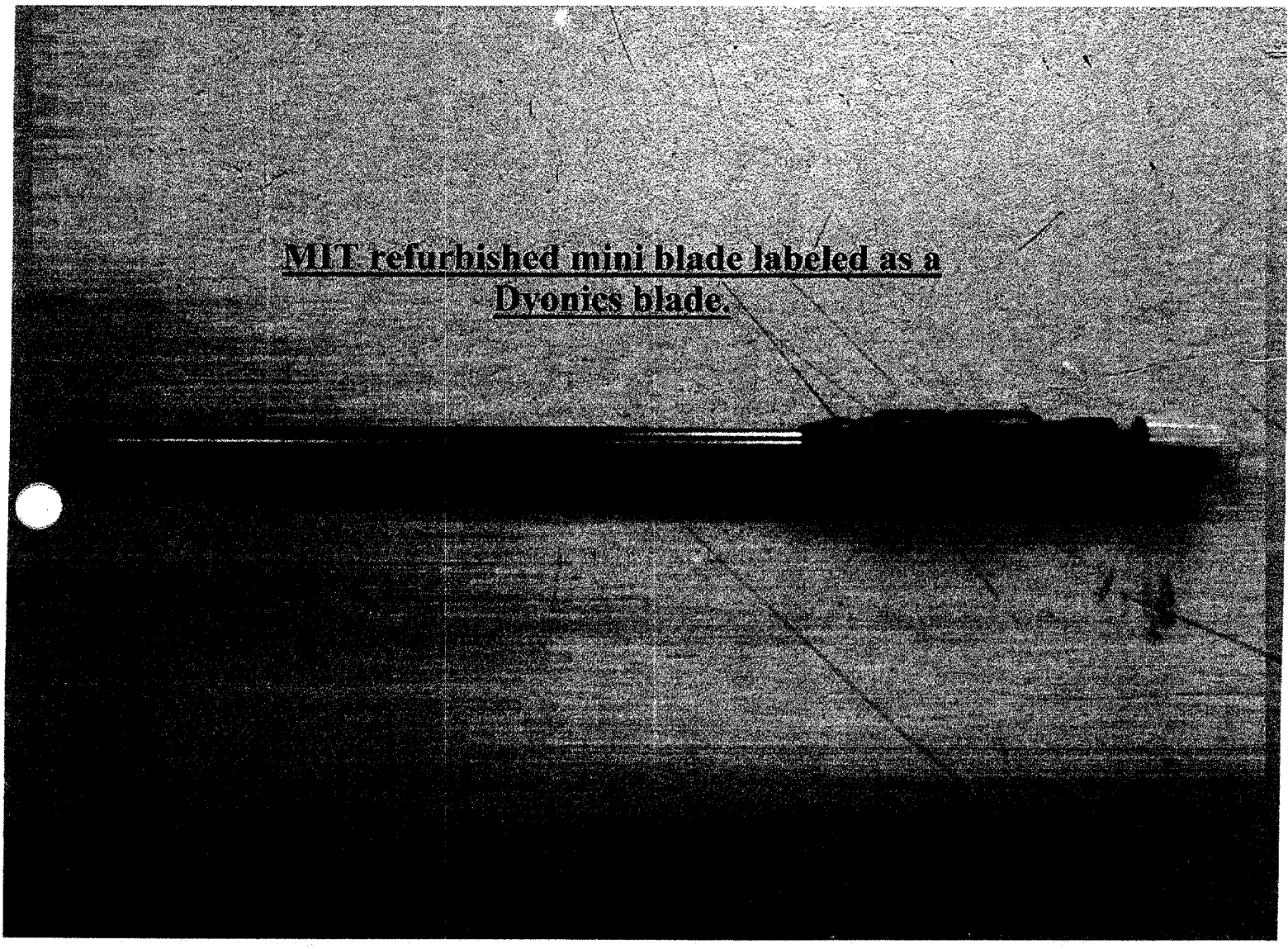
Pic#8
SISS refurbished stonecutter blade,
blood stain evident on inner tube.

[redacted]

ATTACHMENT V

Mislabeled refurbished blade


MIT refurbished blade labeled as a Dyonics blade.
Dyonics mini blades have a "J" groove.


MIT refurbished mini blade labeled as a
Dyonics blade.

ATTACHMENT VI

stryker INSTRUMENTS

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Stryker Instruments Memorandum

Study Objective:

Reuse of single-use devices is a greatly debated issue. The FDA has requested input from hospitals, OEMs (original equipment manufacturers), and third-party reprocessors to help them make a decision about the best way to regulate reuse of single-use devices. To assist the FDA in making an informed decision, Stryker Instruments gathered 211 reprocessed devices from different regions of the country. A team of highly trained engineers reviewed and assessed these devices based on the labeling, device condition, and packaging. In the near future, the quality of the seal and sterility will be examined.

Study Results:

42.7% (90/211) Mislabeled

37.9% (80/211) Compromised Condition

10.4% (22/211) Packaging Flaws

Description of Categories:

Labeling. Engineers examined the part number, original equipment manufacturer's name, dimensions, lot number, and extra wording that was placed on the outside of the reprocessed device. Of the 90 devices that were mislabeled, 77 labels had the wrong dimensions. Another key finding was that 20 devices had the wrong part number. In addition, the wrong original manufacturer's name was on 6 labels. Other errors included wrong device descriptions, adding phrases to the description, and not including a label or instructions for use.

Device Condition. The quality of the flutes, sharpness of the blades, and device cleanliness was examined to determine the condition of the reprocessed device. A total of 80 devices were found to have flaws in their integrity. Twenty-three devices had worn, damaged flutes. It appeared that the attempted re-sharpening by the third-party reprocessor resulted in dull flutes on burs and teeth on saws. A reprocessed mixevac had an inactivated filter due to the EtO gas used by the reprocessor. EtO gas activates the charcoal filter, soaks up the gas, and results in the inability to completely degas. Therefore, the filter becomes inactivated. Other findings included bent devices, broken devices, rusted or dirty mounts, punctured burs, cleaning residue, extra coatings on blades, and severely scratched surfaces.

Packaging. The inner and outer packaging was assessed with magnifying glass for pinholes, punctures, and dirt. Out of 211 devices, 22 had packaging flaws. An additional finding was that most reprocessed rasps did not have a blister, which is used to secure the packaging.

Key to the Reprocessing Spreadsheet

Third-Party Reprocessors

1. Medical Instruments Technology, Inc.
2. Medical Device Services
3. Vanguard Medical Concepts
4. Alliance Medical Corporation
5. Adven
6. Anew Medical Enterprises
7. SterilMed, Inc.

Reprocessed Devices by Third-Party Reprocessors

Part Number	Description	Labeling	Condition	Packaging	Reprocessor	Lot Number	Comments
1608-2-43	2.2 mm Drill	OK	OK	hole	1	01372-0143	
1608-2-7	1.6mm Bur	OK	OK	OK	1	01372-0121	"Osteotomy" is on label
1608-2-7	1.6mm Bur	OK	OK	OK	1	01372-0121	"Osteotomy" is on label
1608-2-49	2.3mm Drill	OK	OK	OK	1	01372-0145	QC on label
1607-2-113	1.2mm Bur	OK	OK	OK	1	01372-0133	
1607-2-107	1.6mm Bur	Mislabeled	OK	OK	1	01372-0131	1.65 on label, actually 1.6
1607-2-57	3.02mm Bur	OK	OK	OK	1	01372-0109	QC, No longer available
1608-2-13	4.7mm Bur	OK	damaged	OK	1	01372-0113	flutes look worn, damaged
1608-2-13	4.7mm Bur	OK	damaged	OK	1	01372-0113	flutes look worn, damaged
1608-2-9	2.3mm Bur	OK	damaged	OK	1	01372-0123	flutes look worn, osteotomy
1608-2-9	2.3mm Bur	OK	damaged	OK	1	01372-0123	flutes look worn, osteotomy
1608-2-9	2.3mm Bur	OK	damaged	OK	1	01372-0123	flutes look worn, osteotomy
1608-2-9	2.3mm Bur	OK	damaged	OK	1	01372-0123	flutes look worn, osteotomy
1608-2-9	2.3mm Bur	OK	damaged	OK	1	01222-0026	flutes look worn, osteotomy
1608-2-9	2.3mm Bur	OK	damaged	OK	1	01372-0123	flutes look worn, osteotomy
1608-2-13	4.7mm Bur	OK	damaged	OK	1	01372-0113	hole in bur,damaged
1608-2-11	3.2mm Bur	mislabeled	damaged	OK	1	01372-0111	3.1 on label, actually 3.2
1608-2-11	3.2mm Bur	mislabeled	damaged	OK	1	01372-0112	3.1 on label, actually 3.2
1608-2-13	4.7mm Bur	OK	damaged	OK	1	01339-0100	flutes look worn, QC
1608-2-13	4.7mm Bur	OK	damaged	OK	1	01372-0113	flutes look worn, QC
1608-2-13	4.7mm Bur	OK	damaged	OK	1	01372-0113	flutes look worn, QC
1608-2-14	4.7mm Bur	OK	damaged	OK	1	01372-0113	flutes look worn, QC
1607-2-17	7.0mm Bur	OK	damaged	OK	1	01372-0105	flutes look worn, Osteotomy
1608-2-7	1.6mm Bur	OK	OK	OK	1	01372-0121	Osteotomy
1607-2-113	1.2mm Bur	mislabeled	dirty	OK	1	01372-0133	Not a Stryker bur, dirt on bur
1607-2-101	2.26mm Bur	OK	OK	OK	2	221522	
1608-2-59	1.5mm Drill	OK	OK	OK	3	235349	worn
277-10-216	1.6mm Bur	mislabeled	OK	OK	3	237928	Not a Stryker bur
1608-2-17	7mm Bur	mislabeled	rusted	OK	1	01372-0117	labeled 8 flute, actually16. Rusted mount
1608-2-17	7mm Bur	mislabeled	OK	OK	1	01372-0117	labeled 8 flute, actually 16
1607-2-17	7mm Bur	OK	OK	OK	1	01372-0105	osteotomy
1607-2-17	7mm Bur	OK	OK	OK	1	01372-0106	osteotomy
1608-2-17	7mm Bur	mislabeled	OK	OK	1	01372-0117	labeled 8 flute, actually 16

Reprocessed Devices by Third-Party Reprocessors

Part Number	Description	Labeling	Condition	Packaging	Reprocessor	Lot Number	Comments
5100-37-113	Small tear cross cut Rasps	Mislabeled	OK	Pinholes?- Need blisters for Rasps	1	01372-0135	Label states 1675-113, actually 5100-37-113;label states 11.10mmx4.7mm, actually 11x5
5100-37-113	Small tear cross cut Rasps	Mislabeled	OK	Pinholes?- Need blisters for Rasps	1	01372-0135	Label states 1675-113, actually 5100-37-113;label states 11.10mmx4.7mm, actually 11x5
5100-37-113	Small tear cross cut Rasps	Mislabeled	dirty	Pinholes?- Need blisters for Rasps	1	01372-0135	Label states 1675-113, actually 5100-37-113;label states 11.10mmx4.7mm, actually 11x5; dirt in mount area
5100-37-113	Small tear cross cut Rasps	Mislabeled	OK	Pinholes?- Need blisters for Rasps	1	01372-0135	Label states 1675-113, actually 5100-37-113;label states 11.10mmx4.7mm, actually 11x5
5100-37-113	Small tear cross cut Rasps	Mislabeled	OK	Pinholes?- Need blisters for Rasps	1	01372-0135	Label states 1675-113, actually 5100-37-113;label states 11.10mmx4.7mm, actually 11x5
5100-37-113	Small tear cross cut Rasps	Mislabeled	OK	Pinholes?- Need blisters for Rasps	1	01372-0135	Label states 1675-113, actually 5100-37-113;label states 11.10mmx4.7mm, actually 11x5
5100-37-113	Small tear cross cut Rasps	Mislabeled	OK	Pinholes?- Need blisters for Rasps	1	01372-0135	Label states 1675-113, actually 5100-37-113;label states 11.10mmx4.7mm, actually 11x5
2296-3-51	5.5mm saw blade	Mislabeled	OK	OK	1	01372-0072	Label states 10mm actually 5.5mm
2296-3-51	5.5mm saw blade	Mislabeled	scratched	OK	1	01372-0072	Label states 10mm actually 5.5mm
2296-3-51	5.5mm saw blade	Mislabeled	OK	OK	1	01372-0072	Label states 10mm actually 5.5mm

Reprocessed Devices by Third-Party Reprocessors

Part Number	Description	Labeling	Condition	Packaging	Reprocessor	Lot Number	Comments
2296-3-51	5.5mm saw blade	Mislabeled	OK	OK	1	01372-0072	Label states 10mm actually 5.5mm
2296-3-51	5.5mm saw blade	Mislabeled	OK	OK	1	01372-0072	Label states 10mm actually 5.5mm
2296-3-51	5.5mm saw blade	Mislabeled	OK	OK	1	00738-0026	Label states 10mm actually 5.5mm
2296-3-51	5.5mm saw blade	Mislabeled	OK	OK	1	01222-0023	Label states 10mm actually 5.5mm
2296-3-51	5.5mm saw blade	Mislabeled	OK	OK	1	01372-0072	Label states 10mm actually 5.5mm
2296-3-115	7mm saw blade	Mislabeled	residue on blade	OK	1	01222-0029	Label states 10mm actually 7.0mm
2296-3-115	7mm saw blade	Mislabeled	residue on blade	OK	1	01012-0035	Label states 10mm actually 7.0mm
2296-33-115	7mm saw blade	Mislabeled	OK	OK	1	01222-0028	Label states 10mm actually 7.0mm
2296-3-125	9mm saw blade	Mislabeled	OK	OK	1	01372-0060	Label states 10mm actually 9.0mm
2296-3-125	9mm saw blade	Mislabeled	residue on blade	OK	1	01372-0060	Label states 10mm actually 9.0mm
2296-3-125	9mm saw blade	Mislabeled	scratched	OK	1	01372-0060	Label states 10mm actually 9.0mm
2296-3-125	9mm saw blade	Mislabeled	OK	OK	1	01506-0026	Label states 10mm actually 9.0mm;states oscillating
2296-3-125	9mm saw blade	Mislabeled	OK	OK	1	01506-0026	Label states 10mm actually 9.0mm;states oscillating
2296-3-125	9mm saw blade	Mislabeled	Bent	OK	1	01372-0060	Label states 10mm actually 9.0mm;blade is bent
2296-3-125	9mm saw blade	Mislabeled	OK	OK	1	01372-0060	Label states 10mm actually 9.0mm
2296-3-206	12mm saw blade	Mislabeled	OK	OK	1	01012-0033	Label states 10mm actually 12mm
2296-3-105	9mm saw blade	Mislabeled	scratched	OK	1	01372-0058	Label states 10mm actually 9.0mm;scratched
2296-3-105	9mm saw blade	Mislabeled	OK	OK	1	01372-0058	Label states 10mm actually 9.0mm

Reprocessed Devices by Third-Party Reprocessors

Part Number	Description	Labeling	Condition	Packaging	Reprocessor	Lot Number	Comments
2296-3-105	9mm saw blade	Mislabeled	scratched	OK	1	01372-0058	Label states 10mm actually 9.0mm;scratched
2296-3-105	9mm saw blade	Mislabeled	broken	OK	1	01372-0058	Label states 10mm actually 9.0mm; broken
2296-3-105	9mm saw blade	Mislabeled	OK	OK	1	01372-0058	Label states 10mm actually 9.0mm
2296-3-103	7mm saw blade	Mislabeled	OK	OK	1	01372-0062	Label states 10mm actually 7.0mm
2296-3-103	7mm saw blade	Mislabeled	OK	OK	1	01339-0072	Label states 10mm actually 7.0mm
2296-3-103	7mm saw blade	Mislabeled	OK	OK	1	01372-0062	Label states 10mm actually 7.0mm
2296-3-103	7mm saw blade	Mislabeled	broken	OK	1	01372-0062	Label states 10mm actually 7.0mm; broken
2296-3-103	7mm saw blade	Mislabeled	OK	OK	1	01372-0062	Label states 10mm actually 7.0mm
2296-3-104	16.4mm saw blade	OK	residue on blade	OK	1	01012-0034	Label only states "saw blade"; residue left on blade
2296-3-104	16.4mm saw blade	OK	residue on blade	OK	1	01012-0034	Label only states "saw blade"; residue left on blade
2296-3-103	7mm saw blade	OK	OK	OK	2	239819	Label states micro-oscillating saw blade
2108-150	Saw blade	OK	dirty	OK	1	01012-0031	Something in package
2108-150	Saw blade	OK	OK	OK	1	01506-0022	
2108-150	Saw blade	OK	OK	OK	1	01012-0031	
2108-150	Saw blade	OK	scratched	OK	1	01012-0031	blade scratched
2108-150	Saw blade	OK	scratched	OK	1	01012-0031	blade scratched
2108-150	Saw blade	OK	scratched	OK	1	01012-0031	blade scratched
2108-150	Saw blade	OK	OK	OK	1	01012-0031	
2108-150	Saw blade	OK	OK	OK	1	01012-0031	
2108-150	Saw blade	OK	OK	OK	1	01012-0031	
2108-150	Saw blade	OK	OK	OK	1	01012-0031	
2108-150	Saw blade	OK	OK	OK	1	01012-0031	
2108-150	Saw blade	OK	no insert line	OK	1	01372-0036	blade worn; no insert line
2108-150	Saw blade	OK	scratched	OK	1	01372-0036	blade scratched

Reprocessed Devices by Third-Party Reprocessors

Part Number	Description	Labeling	Condition	Packaging	Reprocessor	Lot Number	Comments
2108-150	Saw blade	OK	OK	pouch punctured	1	01012-0031	Punctures in pouch
2108-150	Saw blade	OK	scratched	pin holes in inner pouch	1	01012-0031	Pin holes in inner pouch
2108-145	Saw blade	OK	residue on blade	OK	1	01339-0068	Cleaning residue on blade
2108-145	Saw blade	OK	residue on blade	OK	1	01372-0030	Cleaning residue on blade
2108-156	Saw blade	OK	residue on blade	OK	1	01372-0038	Cleaning residue on blade
2108-156	Saw blade	OK	residue on blade	OK	1	01372-0038	Cleaning residue on blade
2108-156	Saw blade	OK	residue on blade	OK	1	01372-0038	Cleaning residue on blade
5100-37-114	Large tear cross cut rasp	mislabeled	OK	need blister for rasps	1	01372-0137	labeled 1675-114, actually 5100-37-114; labeled 11.2x6.81 actually 14x7
5100-37-114	Large tear cross cut rasp	mislabeled	residue	need blister for rasps	1	01372-0137	labeled 1675-114, actually 5100-37-114; labeled 11.2x6.81 actually 14x7; residue near mounting
5100-37-114	Large tear cross cut rasp	mislabeled	OK	need blister for rasps	1	01372-0137	labeled 1675-114, actually 5100-37-114; labeled 11.2x6.81 actually 14x7
5100-37-114	Large tear cross cut rasp	mislabeled	residue	need blister for rasps	1	01372-0137	labeled 1675-114, actually 5100-37-114; labeled 11.2x6.81 actually 14x7;residue on mount
5100-37-114	Large tear cross cut rasp	mislabeled	OK	need blister for rasps	1	01372-0137	labeled 1675-114, actually 5100-37-114; labeled 11.2x6.81 actually 14x7
5100-37-114	Large tear cross cut rasp	mislabeled	OK	need blister for rasps	1	01372-0137	labeled 1675-114, actually 5100-37-114; labeled 11.2x6.81 actually 14x7
1607-2-35	4mm Bur	mislabeled	OK	OK	1	01372-0107	Labeled as Stryker but it is not a Stryker bur

Reprocessed Devices by Third-Party Reprocessors

Part Number	Description	Labeling	Condition	Packaging	Reprocessor	Lot Number	Comments
1607-2-35	4mm Bur	mislabeled	flutes rounded/dull	OK	1	01372-0107	Labeled as Stryker but it is not a Stryker bur; flutes rounded/dull
1608-2-35	4mm Bur	OK	flutes rounded/dull	OK	1	01372-0119	Flutes are dull,rounded
1607-2-1	6mm Bur	OK	flutes rounded/dull	OK	1	01372-0103	Flutes are dull,rounded
1607-2-35	4mm Bur	mislabeled	flutes rounded/dull	OK	1	01372-0107	Labeled as Stryker but it is not a Stryker bur; flutes rounded/dull
1607-2-35	4mm Bur	mislabeled	flutes rounded/dull	OK	1	01372-0107	Labeled as Stryker but it is not a Stryker bur; flutes rounded/dull
1608-2-35	4mm Bur	OK	flutes rounded/dull	OK	1	01339-0103	Flutes are dull, rounded; osteotomy
1607-2-1	6mm Bur	OK	flutes rounded/dull	OK	1	01372-0103	Flutes are dull, rounded; osteotomy
1607-2-1	6mm Bur	OK	flutes rounded/dull	OK	1	01372-0103	Flutes are dull, rounded; osteotomy
1608-2-1	6mm Bur	OK	flutes rounded/dull	OK	1	01506-0029	Flutes are dull, rounded
1608-2-35	4mm Bur	OK	OK	OK	1	01372-0119	osteotomy
1608-2-35	4mm Bur	OK	OK	OK	1	01506-0031	osteotomy
1608-2-35	4mm Bur	OK	OK	OK	1	01506-0031	osteotomy
1607-2-35	4mm Bur	OK	OK	OK	1	01372-0107	
1607-2-35	4mm Bur	OK	OK	OK	1	01372-0108	
1607-2-35	4mm Bur	OK	flutes dull	OK	3	245334	Attempted to resharpen; flutes dull and residue left on them
1675-133	Saw blade	OK	residue	OK	4	16943-0126	Residue on blade

Reprocessed Devices by Third-Party Reprocessors

Part Number	Description	Labeling	Condition	Packaging	Reprocessor	Lot Number	Comments
277-10-216	1.6mm Bur	mislabeled	residue	OK	3	244862	Labeled as Microaire, actually Stryker; Residue on bur
2108-150	Saw blade	OK	scratched	OK	1	01372-0036	Blade scratched;worn (opened)
2108-150	Saw blade	OK	scratched	OK	1	01012-0031	Blade scratched;worn
2108-150	Saw blade	OK	scratched	OK	1	01012-0031	Blade scratched;worn
2108-150	Saw blade	OK	OK	OK	1	01012-0031	worn
2108-150	Saw blade	OK	OK	OK	1	01012-0031	worn
2108-150	Saw blade	OK	OK	OK	1	01012-0031	worn
2108-150	Saw blade	OK	OK	OK	1	01012-0031	worn
2108-150	Saw blade	OK	OK	OK	1	01372-0036	worn
2108-150	Saw blade	OK	OK	OK	1	01372-0036	worn
2108-150	Saw blade	OK	OK	OK	1	01012-0031	
2108-150	Saw blade	OK	OK	OK	1	01012-0031	
2108-150	Saw blade	OK	damaged	OK	1	01012-0031	Edges damaged
2108-150	Saw blade	OK	damaged	OK	1	01372-0036	Edges damaged
2108-150	Saw blade	OK	damaged	OK	1	01372-0036	Edges damaged and scratched
2108-150	Saw blade	OK	OK	OK	1	01012-0031	
2296-33-414	Saw blade	mislabeled	OK	OK	1	01372-0074	Labeled 10mm actually 5.5
2296-33-414	Saw blade	mislabeled	OK	OK	1	01372-0074	Labeled 10mm actually 5.5
2296-33-414	Saw blade	mislabeled	OK	OK	1	01372-0074	Labeled 10mm actually 5.5
2296-33-414	Saw blade	mislabeled	OK	OK	1	01506-0024	Labeled 10mm actually 5.5
2296-3-525	Saw blade	mislabeled	Damaged	OK	1	01222-0032	Labeled 10mm actually 9mm;Dent near cut surface;Mount marks
2296-3-414	Saw blade	mislabeled	Damaged	OK	1	01164-0017	Labeled 10mm actually 5.5mm, thin blade; Dent near cut surface; Mount marks
2296-33-414	Saw blade	mislabeled	Damaged	OK	1	01372-0074	Labeled 10mm actually 5.5mm; Dent near cut surface; Mount marks

Reprocessed Devices by Third-Party Reprocessors

Part Number	Description	Labeling	Condition	Packaging	Reprocessor	Lot Number	Comments
2296-3-525	Saw blade	mislabeled	Damaged	OK	1	01222-0032	Labeled 10mm actually 9mm;Dent near cut surface;Mount marks
2296-3-410	Saw blade	mislabeled	OK	OK	1	01372-0064	Labeled 10mm actually 5.5mm
2296-3-410	Saw blade	mislabeled	OK	OK	1	01372-0064	Labeled 10mm actually 5.5mm
2296-3-410	Saw blade	mislabeled	OK	OK	1	01372-0064	Labeled 10mm actually 5.5mm
2296-3-410	Saw blade	mislabeled	OK	OK	1	01372-0064	Labeled 10mm actually 5.5mm
2296-3-410	Saw blade	mislabeled	OK	OK	1	01372-0064	Labeled 10mm actually 5.5mm
2296-3-410	Saw blade	mislabeled	OK	OK	1	01372-0064	Labeled 10mm actually 5.5mm
2296-3-411	Saw blade	mislabeled	OK	dirty	1	01372-0066	Fuzzy hair in package; Labeled as 10mm actually 9mm
2296-3-411	Saw blade	mislabeled	OK	OK	1	01372-0066	Labeled as 10mm actually 9mm
2296-3-411	Saw blade	mislabeled	OK	dirty	1	01372-0066	Dirt in package; Labeled as 10mm actually 9mm
2296-3-412	Saw blade	mislabeled	OK	OK	1	01372-0068	Labeled as 10mm actually 5.5mm
2296-3-412	Saw blade	mislabeled	OK	OK	1	01372-0068	Labeled as 10mm actually 5.5mm
2296-3-412	Saw blade	mislabeled	OK	OK	1	01372-0068	Labeled as 10mm actually 5.5mm
2296-3-412	Saw blade	mislabeled	OK	OK	1	01372-0068	Labeled as 10mm actually 5.5mm
2296-3-412	Saw blade	mislabeled	OK	OK	1	01372-0068	Labeled as 10mm actually 5.5mm
2296-3-412	Saw blade	mislabeled	OK	OK	1	01372-0068	Labeled as 10mm actually 5.5mm
2296-3-412	Saw blade	mislabeled	OK	OK	1	01372-0068	Labeled as 10mm actually 5.5mm

Reprocessed Devices by Third-Party Reprocessors

Part Number	Description	Labeling	Condition	Packaging	Reprocessor	Lot Number	Comments
5305-25-123	Saw blade	OK	OK	OK	1	01372-0044	
5305-25-124	Saw blade	OK	OK	OK	1	01372-0046	
5305-25-124	Saw blade	OK	OK	OK	1	01372-0046	
5305-25-124	Saw blade	OK	OK	OK	1	01372-0046	
5305-25-124	Saw blade	OK	OK	OK	1	01372-0046	
5305-25-125	Saw blade	OK	OK	OK	1	01372-0048	
5305-25-125	Saw blade	OK	OK	OK	1	01372-0048	
5305-25-125	Saw blade	OK	OK	OK	1	01372-0048	
5100-37-115	Small tear Rasp	mislabeled	OK	hole	1	01372-0139	Labeled as 1675-115 11.2x5.82mm actually 5100-37-115 11x5; hole in inner pouch rightside of flutes
5100-37-115	Small tear Rasp	mislabeled	OK	OK	1	01372-0139	Labeled as 1675-115 11.2x5.82mm actually 5100-37-115 11x5mm
5100-37-115	Small tear Rasp	mislabeled	OK	OK	1	01372-0139	Labeled as 1675-115 11.2x5.82mm actually 5100-37-115 11x5mm
5100-37-115	Small tear Rasp	mislabeled	OK	OK	1	01372-0139	Labeled as 1675-115 11.2x5.82mm actually 5100-37-115 11x5mm
5100-37-115	Small tear Rasp	mislabeled	OK	OK	1	01372-0139	Labeled as 1675-115 11.2x5.82mm actually 5100-37-115 11x5mm
2108-145	Saw blade	OK	OK	OK	1	01372-0030	
2108-145	Saw blade	OK	OK	OK	1	01372-0030	
2108-145	Saw blade	OK	scratched	OK	1	01372-0030	Scratched
2108-145	Saw blade	OK	OK	OK	1	01372-0030	
2108-145	Saw blade	OK	scratched	OK	1	01372-0030	Scratched
2108-145	Saw blade	OK	OK	OK	1	01372-0030	
2108-145	Saw blade	OK	OK	OK	1	01372-0030	
2108-145	Saw blade	OK	OK	OK	1	01372-0030	
2108-302	Saw blade	OK	OK	OK	1	01012-0015	
2108-145	Saw blade	OK	OK	OK	1	01372-0030	
2108-145	Saw blade	OK	OK	OK	1	01506-0021	

Reprocessed Devices by Third-Party Reprocessors

Part Number	Description	Labeling	Condition	Packaging	Reprocessor	Lot Number	Comments
2108-192	Saggital Saw	mislabeled	OK	OK	1	01012-0032	Labeled reciprocating saw, actually saggital saw
2108-185	Saw blade	OK	OK	OK	4	17458-0009	
2108-145	Saw blade	OK	OK	OK	1	01372-0030	
5100-37-116	Large tear rasp	mislabeled	residue	OK	1	01372-0141	Labeled as 1675-116 11.7x6.99mm, actually 5100-37-116 12.5x7mm; residue on flutes
5100-37-116	Large tear rasp	mislabeled	residue	OK	1	01372-0141	Labeled as 1675-116 11.7x6.99mm, actually 5100-37-116 12.5x7mm; residue on flutes
2108-310	Saw blade	OK	scratched	OK	5	3762771	Resharpened-teeth are no longer "aggressive"; blade scratched
2108-100	Saw blade	OK	OK	OK	4	17448-0052	
2108-109	Saw blade	OK	OK	Hole in inner pouch	1	01372-0024	Inner pouch has hole
2108-111	Saw blade	OK	OK	OK	1	00937-0027	
2108-100	Saw blade	OK	OK	OK	4	17643-0067	
2108-118	Saw blade	mislabeled	OK	OK	2	192713	Labeled as 25x75mm actually 25x 79.5mm
2108-328	Saw blade	OK	coated	OK	6	6038	coated teeth on blade
2108-204	Saw blade	OK	damaged coated and residue	OK	6	6049	Coated teeth on blade and residue on blade; Triangular hole on blade-may not be a Stryker blade
206-10	Mixevac	mislabeled	damaged	OK	7	24699-014	Inactivated filter due to EtO gas; no instructions for use included.

Manufacturer	Part Number	Description	Labeling	Condition	Packaging	Reprocessor	Lot Number	Comments
Micro-Aire	ZO-7053	Saw blade	OK	OK	Punctured pouch	4	16110-0028	Blade puncturing pouch
Micro-Aire	ZS-033	Saw blade	OK	Scratched	OK	4	13168-0024	Blade is scratched
Micro-Aire	ZS-7053	Saw blade	OK	OK	OK	4	17874-0026	
Micro-Aire	K-38	4mm Bur	OK	OK	OK	4	15535-0006	
Micro-Aire	SR-007	Saw blade	OK	worn	Punctured pouch	4	15170-0162	Pouch is punctured by blade
Micro-Aire	ZR-058	Saw blade	OK	Scratched	OK	1	01012-0012	Blade is scratched and worn
Micro-Aire	ZR-058	Saw blade	OK	OK	OK	1	01012-0012	
Micro-Aire	ZR-058	Saw blade	OK	OK	residue	1	01012-0012	Residue on pouch
Micro-Aire	ZO-7053	Saw blade	OK	worn	OK	4	13157-0036	Teeth look worn
Micro-Aire	ZO-7053	Saw blade	OK	OK	OK	4	16110-0028	
Komet	KM-25K	Saw blade	OK	OK	OK	4	17256-0025	
Komet	KM-24K	Saw blade	OK	OK	OK	1	01372-0083	
Komet	KM-24K	Saw blade	OK	OK	OK	1	01372-0080	
Komet	KM-24K	Saw blade	OK	OK	OK	1	01372-0080	
Komet	KM-25K	Saw blade	OK	scratched	OK	1	01372-0080	
Komet		Saw blade	OK	OK	OK	1	01372-0083	
Unknown	Unknown	Saw blade	No label	OK	OK	1	?	No label on package.

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